UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	**MD-15-02641-PHX-DGC**
	Phoenix, Arizona
	May 29, 2018
Doris Jones, an individual,	
Plaintiff,	
v.	CV-16-00782-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 9 - A.M. SESSION

(Pages 1866 - 1992)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
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A P P E A R A N C E S

For Plaintiff:

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
By: **SHANNON L. CLARK**, ESQ.
By: **C. LINCOLN COMBS**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Lopez McHugh, LLP
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
214 Flynn Ave.
Moorestown, NJ 08057

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
By: **LAURA E. SMITH**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

For Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.** ESQ.
By: **ELIZABETH C. HELM**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Nelson Mullins Riley & Scarborough.
BY: **JAMES F. ROGERS**, ESQ.
1320 Main St.
Columbia, SC 29201

Snell & Wilmer
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

EXAMINATION

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1926	Romney, 01/18/2017, Exhibit 2061 - 8/6/2014 E-mail from Schyler Smith, Field Manager for BPV in Washington-Idaho-Montana, to Kim Romney, Subject redacted, relaying that a redacted doctor had placed a Meridian in the past year and discovered at retrieval that an arm fractured, which imaging confirmed had occurred within 1 week of placement, and was now wondering if he should try to remove the filter or leave it in. Van Vleet forwarded to Treratola in a high importance e-mail on 8/7, requesting that he contact the doctor on Bard's behalf	1891
2105	Trerotola, 01/20/2017, Exhibit 692 - 4/30/2015 E-mail from Dr. Trerotola to John Van Vleet, forwarding an article from Forbes Magazine about ALN filters entitled "Effect of a Retrievable IVC Filter Plus Anticoagulation vs. Anticoagulation Alone on Risk of Recurrent PE: A Randomized Clinic Trial". Per Trerotola, "not good for ALN...and maybe not good for the industry". The article was discussed through 5/4, as	1891

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6991	FDA Safety - Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use, 08/09/2010	1965
6992	FDA Safety Communications, Removing Retrievable Inferior Vena Cava Filters. 05/06/2014.http://wayback.archive-it.org/7993/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm	1970

08:30:08

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:30:12

THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Counsel, do you have things we need to talk about before we get started today?

08:30:31

MR. O'CONNOR: Yes, we do, Your Honor.

MR. CLARK: We have a couple of things. I don't know how many Bard has.

Your Honor, I think, as we foreshadowed last week, we do have an issue with respect to the complaint detail summary

08:30:48

at the end of certain monthly management reports. And we understand the Court's concern about the 403 analysis that was done with respect to the 1006 summary.

By our count there are or will be 12 monthly management reports into evidence. We do think it's important

08:31:07

for the jury to be able to see a few examples of the complaint detail that was going into these monthly management reports because that is a direct line to the decision makers in the company.

We have broached this with Bard. Their position, or

08:31:23

its position, is that that would run afoul and sort of be too

08:31:28 cumulative of other information. We don't think that's the case. We do understand the concern about having too much, but of the 12 we propose four or five be allowed to include the complaint detail because this is the only area where we can 08:31:41 show the jury that this is what is going to the decision makers. We have the complaint summaries, we have the TrackWise data, and what's going to be in the 1006 summary. But there's no -- we don't that have link that all of these -- this information is going to the decision makers. So I think 08:31:57 that is an important component there.

So we want to try to find some balance there where we can at least show the jury this is the type of information that was going there and then make redactions for the other eight or nine of those. But we do think we should be allowed 08:32:12 to have a few of those in there, and we want your decision on that so we can get those redactions going.

THE COURT: Well, I think to make that decision I think I need to see both the 1006 summary and the all of the exhibits you're proposing to put in as monthly management 08:32:25 reports so I can look at the exhibits and decide --

MR. CLARK: Would it be okay with the Court if we provided that information to you before the lunch hour?

THE COURT: Yes.

MR. CLARK: Okay.

08:32:34 THE COURT: But what I'll need to know is exactly

what it is you're proposing to put in. So I think you need to give me the 12 exhibits with the four or so you think should have the complaint summaries attached, as well as the 1006 summary.

MR. CLARK: We can do that.

THE COURT: And I'll hear from Bard now about what they think should be excluded, but I think I need to lay them side by side in order to make a decision.

MR. CLARK: That makes sense.

I have one other issue. I don't know if you want to take them both --

THE COURT: Well, let's hear from defense counsel.

Is it your view that none of the complaint summaries should be included with the monthly management reports?

MR. NORTH: Right, Your Honor. Our belief is that by allowing the 40 events in the separate summary, that that provides the sampling the Court had talked about, and the management reports in essence sort of circumvent that limitation by introducing several dozen more.

THE COURT: Okay. So if you could have those exhibits for me at the noon hour, I'll look at them.

MR. CLARK: The other issue, Your Honor, was just to kind of circle back to the FDA warning letter. We would like to use that with certain witnesses, if possible. I don't know if you've -- if your tally has allowed you to make a decision

08:33:40 on that --

THE COURT: When is it that those witnesses are on?

MR. CLARK: It could come up as early as Mr. Carr this afternoon, and certainly with Mr. Modra tomorrow that we 08:33:48 would like to use that.

THE COURT: Okay.

Is Mr. Carr coming on this afternoon?

MR. NORTH: Mr. Carr is coming this afternoon. Mr. Modra is the person that is most knowledgeable. He's 08:33:59 coming tomorrow.

THE COURT: What time do you expect to get to Mr. Carr?

MR. NORTH: He's our fourth witness today. So assuming we get to him it probably wouldn't be until 3 o'clock 08:34:10 or so.

THE COURT: And how much direct do you expect to have with him?

MR. NORTH: At least an hour to an hour and a half.

THE COURT: Why don't you give me a sense, if you 08:34:21 would, when we break at the noon hour as to whether you think you'll finish your direct by the end of the day on Mr. Carr. If so, I'll look back at the FDA warning issue over the lunch hour.

MR. NORTH: Okay.

08:34:34 MR. O'CONNOR: Your Honor, I just wanted to remind

you that last week we raised at the sidebar the whole issue about opening the door to the cephalad migration based upon the IFU discussion that defense counsel had with Dr. Hurst, pointing out and bringing attention to the morbidly obese patient statement in that IFU. You were going to rule on it.

Mr. North gave some articles. We don't think they're applicable or that there's any evidence to show that those were considered. We believe the evidence has shown that everything Bard has done in this case was response to that serious problem caused by the cephalad migration deaths, and that by pointing half the story out to the jury, we feel that now the ruling that was made that was intended to protect the defendants from prejudice has now been used somewhat as a sword against us and evidence that really should be told a complete story and put in context with why they did things isn't being told, and the inference is that they've done very reasonable things for relatively minor incidents.

So I just want to remind you, number one, that you had put that on hold and you were going to rule on that. But that's our position.

THE COURT: Okay.

Counsel, I don't have those articles that you submitted. If they're up here, they've been lost. Do you have other copies?

MS. HELM: Mr. North's looking for them, Your Honor.

08:36:20 THE COURT: All right. While he's looking for those, are there any other matters that we need to talk about?

MR. O'CONNOR: Along the same lines, Mr. Lopez was going to talk about what happened in the DeFord deposition.

08:36:33 MR. LOPEZ: Morning, Your Honor.

THE COURT: Go ahead, Mr. North, bring those up, would you.

Go ahead, Mr. Lopez.

MR. LOPEZ: Yes, Your Honor. On Friday I think one

08:36:52 of the last depositions that was played was Mr. DeFord. And I've got the transcript here, part of the transcript that was played.

And he testified that, and he was talking about the Recovery filter, that the device was adding value. It

08:37:08 couldn't stop a massive thrombus, just like your seat belt can't stop, and he went on about the fact that the Recovery filter was saving lives.

And then he stated that: I think the risk to patients was absolutely evaluated but the decision was made

08:37:22 that the product continued to add value and shouldn't be placed on hold.

Then he said that: The conditions wanted a device they could retrieve. It wasn't a company decision. We're not going to put it on hold because we're selling a retrievable

08:37:40 product. It was the belief and our continued belief that the

product added unique special value and patients lives were being saved.

And I can go on and on, but the point is, Your Honor, throughout this testimony he says it again, that the technology was saving many more lives than it was unable to save. And if we took it off the market and did not have the technology available, then that would further increase the risk to patients versus decrease the risk to patients.

Then he says: We certainly had another vena cava filter on the market, the Simon Nitinol filter, very different technology, certainly known to prevent pulmonary embolism death, but didn't have all the features and benefits of the Recovery.

And I've marked -- I can go on and read this, Your Honor, but I've got five or six more places where he basically testified that the reason they left the Recovery device on the market because it was saving more lives and preventing -- than the lives it was putting at risk.

And I've got eight or nine places in here where he left that impression with the jury.

The real evidence in the case is that there is no evidence. I asked Ms. Hudnall that at her -- and which we played in trial, that the Recovery filter ever stopped a thrombus that might have taken someone's life. They don't know. What we do know is that there --

08:39:08 THE COURT: I think what Ms. Hudnall said is you can't know.

MR. LOPEZ: You can't know.

THE COURT: Not that they don't know, but there's no

08:39:14 way to monitor it.

MR. LOPEZ: Right. In other words, they have -- there's no data about any patient whose life was saved who had a Recovery --

THE COURT: But there can't be any such data.

08:39:26 MR. LOPEZ: That's the point. But he kept saying that --

THE COURT: No, the point isn't that they could have collected it and didn't; her point was you can't. It's impossible to know. You're trying to prove something that

08:39:36 can't be proven because there's no way to detect when a thrombus gets caught by a clot.

MR. LOPEZ: Well, there is a way that you could have known that had you taken appropriate steps to --

THE COURT: Well, I think her point was only if you

08:39:48 have somebody on 24-hour monitoring will you ever know if the filter catches a clot.

MR. LOPEZ: Right. I understand. But the point is there is no evidence that it saves lives. And we do have evidence in the case, it's not been countered yet, when you

08:40:02 look at a retrospective review of patients, Dr. Rogers, a

defendant -- a defense expert, wrote an article that says looking at a 30-million-patient population, there has been no change in PE fatalities with or without the use of filters.

What we do know is that the Recovery has a history of having been hit with clots, that's the very clots that they're supposed to prevent from causing a fatal PE, that once challenged get -- that migrate to the heart and actually take lives.

And I think that the impression this jury has is that the Recovery filter was a lifesaving device when, in fact, the only evidence in the case that -- it doesn't exist now, but you know the evidence exists -- is that it takes a life. One month -- one per month on average over a very short period of time, that when it does get hit by a PE, a large PE, it doesn't work. And it results in death.

And the jury doesn't know that right now. I think that is as much as anything that's happened in this case, it's opened the door to allow us to get that evidence in front of the jury.

THE COURT: Well, let me ask this question, Mr. Lopez: Let's say the jury knew that.

MR. LOPEZ: Okay.

THE COURT: How does that help prove that the Eclipse filter was defectively designed or defectively warned about?

MR. LOPEZ: Your Honor, as you know, our theory has

been and will continue to be that the Recovery -- if there's no Recovery filter, there's no Eclipse. That the Recovery filter was the predicate device for the G2 and the G2 was the predicate device for the Eclipse.

08:41:55 Even Dr. Tillman agreed that if you're selling an adulterated product, it is being illegally marketed and cannot be used as a predicate.

There's no better evidence that that was an inappropriate predicate than the 19 deaths that the Recovery

08:42:11 caused, I think it's 19, prior to the G2 being cleared to be marketed into the U.S. consuming public.

And the jury doesn't know that. They just think that there's something wrong with the design of the Recovery that caused some injury and harms, and that Bard did what a prudent

08:42:33 manufacturer would do, and that is redesign it and sell the G2, when, in fact, the evidence is very strongly that there's no way they should have been selling the Recovery or had it around to be the predicate device for the G2.

If the G2 had used the Simon Nitinol filter as its

08:42:54 predicate, this would be a much different set of circumstances that we should be allowed to argue. And we can't.

THE COURT: Okay. I understand that point.

MR. LOPEZ: Thank you, Your Honor.

MR. NORTH: Your Honor, Dr. DeFord was responding, as

08:43:10 I recall, to some questions posed by plaintiff's counsel in

08:43:15 the deposition clip as to why the Recovery filter was not being taken off the market, and he said it was the company's determination that the risks were outweighed by the benefits. He actually acknowledged quite honestly in that particular
08:43:27 testimony that there had been some catastrophic events, without going into detail.

He mentioned that there had been instances of clots overcoming and overburdening the filter. But that they still determined that the risks were outweighed by the benefits. I
08:43:44 don't believe that opens the door to the parade of evidence they now want to put in about all of the details of the cephalad migrations.

This Court held from the very beginning prior to this case that they could present evidence that complications with
08:44:01 these devices, including the Recovery filter, can lead to death. And they have done that throughout this case. And that's also all that Dr. DeFord was acknowledging is that there can be catastrophic adverse events.

And then he said we did not -- we canceled the
08:44:21 product hold and put the product -- allowed the product to be sold because we determined that the risks were outweighed by the benefits.

Ironically, at the time the product hold even came into issue, there were only two migration deaths, as I recall.
08:44:35 Two, maybe three. Not the 19 that Mr. Lopez is talking about.

08:44:39 But in any event, we do not believe that opens the door to this long parade of evidence they wish to put in, particularly in a case involving an Eclipse filter two generations removed from the Recovery filter. It is in the 08:44:55 record, they have their evidence, and have long had their evidence, that these complications can lead to death, and therefore we don't believe that the door should be opened any further.

THE COURT: Okay. Well, I understand the parties' 08:45:07 positions on this issue. I will think about it further in light of what's been said this morning.

Is there anything else we need to cover before we get the jury?

MR. O'CONNOR: Yes, one more issue Mr. Combs has.

08:45:23 MR. COMBS: Morning, Your Honor.

THE COURT: Morning.

MR. COMBS: I'm not sure how much argument you want to hear, I'm prepared to talk about it. But the issue is with the defendants wanting to call five interventional 08:45:36 radiologists in their case. We already heard from Dr. Grassi, Dr. Stein, and today we'll hear from Dr. Morris.

And they also want to play the videos of Drs. Trerotola and Stavropoulos, who I think were played in Booker, so you're familiar with what they were going to say. 08:45:55 And we would just argue that those are cumulative testimony,

08:45:58 as well as Drs. Stavropoulos and Trerotola, their opinions lack relevance to this case regardless of whatever the relevance was in Booker where they were played.

So we would just object that five IRs is well beyond
08:46:15 cumulative evidence.

THE COURT: Why do they lack relevance?

MR. COMBS: I'm sorry?

THE COURT: Why do they lack relevance?

MR. COMBS: They don't know anything about this case,
08:46:23 they don't know anything about the goings-on between -- they were deposed in this case because plaintiffs were seeking evidence of interactions between them and Bard.

That's not what they're being offered for. They're just being offered for pure expert opinions on their
08:46:36 experiences with Bard filters and their beliefs on filters are great and safe and all those kinds of evidence and opinions, which are not only expert opinions from paid Bard consultants, but also entirely duplicative and cumulative of evidence we've already heard or will hear today from Dr. Morris.

08:46:56 You know what Dr. Morris is going to testify on today because it's the same report as Booker.

THE COURT: You said twice that I know. I have -- I will tell you I have zero memory about what any of those three experts will say.

08:47:10 MR. COMBS: Fair enough, Your Honor.

08:47:12 THE COURT: I can go back and look at my notes from Booker, but as I stand here I don't have even an iota of memory of what they will say.

MR. COMBS: Fair enough, Your Honor.

08:47:22 Dr. Morris had a general report --

THE COURT: Let's do this in three minutes because I still have to take care of a matter before we start.

MR. COMBS: Understood, Your Honor.

We submit the five interventional radiologists

08:47:32 opining about Bard filters and their benefits and their opinions on them is well beyond cumulative.

THE COURT: So you think they're being called to say, I think Bard filters have value, I think they're good filters, I use them?

08:47:49 MR. COMBS: Yes, that's exactly what they're going to say. And then you have additional gratuitous opinions like Dr. Trerotola preferring the Simon Nitinol filter, Simon frightenol filter, which I'm sure you're familiar with from Mr. North's closing in Booker.

08:48:07 So these are all expert opinions. They're nothing directly relevant to this case. And, actually, Dr. Stavropoulos in his deposition, most of his testimony deals with, like, perforation, grade 3 perforations and things which aren't relevant to this case.

08:48:20 THE COURT: Okay.

08:48:22 MR. NORTH: Your Honor, we are very mindful of the Court's general admonition about cumulative experts. Dr. Grassi spoke to the SIR guidelines. Dr. Stein had looked at the specific records of the plaintiff in this case and 08:48:35 talked about that. And Dr. Morris is talking about the general use of IVC filters.

The two depositions he's complaining about are two physicians that were deposed by the plaintiffs as fact witnesses. They've never been designated by either side as an 08:48:52 expert. They were deposed at length. And we have like eight- to ten-minute clips of them that we wish to play. And they're not offering expert opinions; they're talking about their personal experiences with filters in general.

THE COURT: Well, the problem I have is I'm hearing 08:49:06 about this ten minutes to 9:00 on the day the evidence is going to be presented. I have no time to go look at the depositions, look at the reports, and decide if it's cumulative. I just can't do that.

And I certainly can't say, well, I think you're more 08:49:19 believable this morning, Mr. Combs, than Mr. North. I mean, the only way I can make that decision is to actually look at the evidence, and it is impossible to do it with ten minutes until the jury comes in.

So I'm afraid I'm not in a position to grant any 08:49:33 relief on that. I'm going to have to assume what the

08:49:36 defendants are saying is correct because I can't look at anything to refute it before we start trial in ten minutes.

If this comes up in another trial, you need to raise it far enough in advance so I've got time to look at the 08:49:50 transcripts and make a judgment as to whether there's a cumulative expert opinion. And that's where it matters. That's where I've said you get one expert per side on an issue. But on fact witnesses, we've had lots of cumulative evidence on both sides from fact witnesses. Not to the point, 08:50:09 in my view, where we've had a 403 problem, but there's been lots of repetition on questioning by plaintiffs and defendants of witnesses who are fact witnesses.

MR. COMBS: Well -- okay. I guess, Your Honor, my only response to that is it puts plaintiffs in a little bit of 08:50:25 a dilemma. If we bring it up too early before the other IRs have testified, then it's not ripe yet. We don't know what they're going to say. How --

THE COURT: If you want me to look at it and they confirm they're going to call, I'll look at the transcript and 08:50:37 I'll look at the report and I'll rule on it. I'm not going to say don't bother me about that until ten minutes before we start trial on the day the witnesses are going to be called. That just doesn't leave any time to do it. And I don't have a way to make a ruling based on what I'm hearing from you with 08:50:51 now eight minutes to go before we get the jury in. It's just

08:50:54 not possible.

MR. COMBS: Understood, Your Honor.

THE COURT: I will come in when we get the jury in the courtroom in eight minutes. Hopefully, folks will be on

08:51:02 time. There was real traffic problems coming into the city this morning from the east side, so hopefully we haven't lost any jurors.

(Recess was taken from 8:51 to 9:00. Proceedings resumed in open court with the jury present.)

09:01:12 THE COURT: Thank you. Please be seated.

Good morning, ladies and gentlemen.

JURORS: Good morning.

THE COURT: Thanks for being here this morning. Hope you had a good weekend.

09:01:18 We will carry on. We believe we're on schedule to get the case wrapped up this week, and so we're going to keep forging ahead.

Ms. Helm.

MS. HELM: Thank you, Your Honor.

09:01:27 Before we call our first witness, both parties have some exhibits to admit. Defendants move to admit Exhibit 5333, 5335, 5334, 5336, 5488, 5587, 5593 subject to redactions, 5602 subject to redactions, 5612 subject to redactions, 5923, 5942, 8358, 8368, 8373, and 8575.

09:02:27 THE COURT: Any objection?

09:02:30 MR. CLARK: Plaintiff has none.

We do have a few of our own exhibits to seek admission of.

THE COURT: Okay.

09:02:34 Those are admitted.

(Exhibits 5333, 5335, 5334, 5336, 5488, 5587, 5593, 5602, 5612, 5923, 5942, 8358, 8368, 8373, 8575 admitted.)

MR. CLARK: Plaintiff would offer 4415, 1140 subject to redaction, 588, 691, 1036, 1500, 1926, 2105, 2252, and

09:03:02 5290.

MS. HELM: No objection, Your Honor.

THE COURT: Okay. Those are admitted subject to redaction.

(Exhibits 4415, 1140, 588, 691, 1036, 1500, 1926, 2105,

09:03:10 2252, 5290 admitted.)

MS. HELM: Your Honor, at this time defendants call Dr. David Feigal.

Your honor, while we get Dr. Feigal, may I move the flip chart over?

09:03:24 THE COURT: Yes.

THE COURTROOM DEPUTY: Sir, if you'll stand right there and raise your right hand.

THE COURTROOM DEPUTY: Doctor, please state your name and spell your last name.

09:04:10 THE WITNESS: David William Feigal, Jr. The last

name is spelled F-E-I-G-A-L.

DAVID W. FEIGAL, JR., M.D.,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Morning, Doctor.

A Good morning.

Q Would you please introduce yourself and tell the ladies and gentlemen of the jury where you live?

A My name is David William Feigal, Junior, and I live just a little bit north of Thousand Oaks, California.

Q And what is your profession? What is your medical specialty?

A I'm a physician, an internist and a clinical epidemiologist.

Q And what is epidemiology? What does an epidemiologist do?

A Epidemiology is the study of the patterns of diseases in populations. The original word came from epidemics. But it is much broader than that now, and so what epidemiologists do is they look at the patterns of diseases or medical conditions or the effects of medical treatment.

Q And would you explain what education and training you have in the field of clinical epidemiology, please.

A After I finished my internship and residency, I spent a

09:05:27 couple of years on the faculty at UC Davis in the department of medicine, and then I went back and did a clinical epidemiology fellowship at University of California, San Francisco and the University of California, Berkeley. It 09:05:39 was a joint program. Two-year program, included getting a master's in public health, and two years of coursework, and then some practical research.

Q Over the course of your profession, have you continued to receive training in the field of epidemiology, on-the-job 09:05:52 training?

A Well, I have. After I completed the fellowship, I actually became the deputy director of the program that I had been in. It was the Andrew Mellon Scholars and Clinical Epidemiology. I was the deputy director for that program. 09:06:08 And I was a member of the faculty of the department of epidemiology at the University of California, San Francisco. And throughout my career, I have done epidemiological research, used those skills later in my career when I was at FDA. Skills that I've used again and again in assessing 09:06:28 product effectiveness and product safety.

Q Have you ever consulted with medical device companies as an epidemiologist?

A I have. I have been asked to help them design studies, to help them design their programs for monitoring the safety of 09:06:46 their products in the marketplace. Design studies that take

09:06:49 place before the products are approved for use. So I've done quite a bit of that.

Q Have you actively -- have you practiced medicine as a clinical practitioner?

09:07:03 A Yes. My practice was always part of a university practice. I was first at UC Davis, and as the faculty there about a third of my time was seeing patients. Much of that my own patients, but also with the students and the interns and residents.

09:07:19 And then, similarly, when I moved to UC San Francisco, and then eventually my wife was recruited to UC San Diego, so I followed her there. And I was on the department of medicine there, all during those approximately 12 years. About a third of my time was in direct patient

09:07:37 care, both inpatients and outpatients in clinical research.

Q And do you still hold an active medical license?

A I do. I've been continuously licensed in California since I finished my training.

Q And are you board-certified in any discipline?

09:07:51 A Yes. I'm board-certified in internal medicine, and then I have a master of public health in epidemiology.

Q You mentioned you worked with the FDA. That is the Food and Drug Administration; is that right?

A That's right.

09:08:01 Q Would you briefly summarize the positions you held with

09:08:04 the FDA and over what period of time.

A Sure. Makes sense if I back up just a little.

When I was at San Francisco General Hospital, it was 1983 and I was doing cardiovascular research, and the AIDS 09:08:18 epidemic came along and we had no idea what it was. And several of my friends who are also epidemiologists began studying it, began finding out what the disease was, and one thing led to another and I actually began doing studies for products that would help people, mostly to treat the 09:08:38 infections that they were getting from HIV.

And that work actually led to an approval of a product by FDA, old product, and led to my being asked to be on advisory committees for antiviral drugs.

And when a position opened in 1991, I applied. It 09:08:56 was a position of being the director of antiviral drugs, which was responsible for all the AIDS products and herpes and influenza and fungal infections and a lot of other things. And they offered me the position and I took that. And my wife -- I followed my wife to San Diego, she followed me to 09:09:17 Washington, went to the National Cancer Institute, and I spent the next 12 years in FDA. First five years in center for drugs, where probably the drugs that were the cornerstone of HIV therapy were first approved during that -- in that era.

So it was a very exciting time. And then I worked in 09:09:34 the Center for Biologics, blood, vaccines, those types of

09:09:38 products.

And for the last five years I was at FDA, I was the director of the Center for Devices and Radiological Health. So that was a group of about 1200 people, 1200 staff, with 09:09:48 research laboratories and product approval responsibilities and monitoring responsibilities.

So that was a period from 1992 to 2004.

Q You mentioned the Center for Devices and Radiological Health. What is the role of the Center for Devices and 09:10:04 Radiological Health within the FDA?

A Well, there's three centers that deal with products for human medicine: Drugs, Biologics, and Devices. So Devices has -- has the equipment, the implants, the X-ray machines, the MRI machines, the hospital supplies, and a wide, wide 09:10:24 range of different types of products. And then it's also combined with a radiological health program, which is responsible for the safety of not just medical products, but consumer products that emit radiation, like cell phones, which use microwaves, microwave ovens, theft detection devices. So 09:10:44 very broad range of products.

Q In addition to your medical practice and your work at the FDA, have you also lectured or presented lectures to professional organizations on topics involving medical devices?

09:10:56 A I have. I have done quite a bit of lecturing. FDA does

09:11:00 quite a bit of outreach, and so I spoke at universities, trade associations, before governmental bodies. I was on governmental panels and commissions.

And then since leaving FDA, I've continued to speak. 09:11:13 And then I teach -- in fact, when we -- when I left FDA, this time I followed my wife, who got a job at TGen, couple blocks from here, Translational Genomics Institute, and I started as a volunteer teacher at Arizona State University.

Q And are you still a part-time resident of Arizona?

09:11:33 A I am. We have a house down in Ahwatukee, which nobody outside of Phoenix knows where that is. But south side of town. We spend about a third of our time here.

Q And as a physician and epidemiologist, have you conducted medical research studies yourself?

09:11:52 A Yes, I have. I've been principal investigator on a large number of studies, coinvestigator on hundreds. Have, at FDA, looked at the design of studies both before approval and after approval. And I'm part of a consulting group that works with small startup companies and help them design their studies. 09:12:15 So I've been doing clinical trials and other types of studies of therapeutic products for 35 years.

Q Have the results of your research and studies been published?

A Yes. When I went into FDA, I stopped doing original 09:12:31 research, but up to that time there were about 50 or 60

09:12:36 publications in the peer-review literature. Many of those -- most of those were epidemiologic studies. And since that time I've also had some publications, but they've been more -- they haven't been related to studies, they've been more
09:12:49 commentaries and editorials.

Q In your professional career, in addition to publishing, have you had responsibility for evaluating studies of adverse events associated with drugs or medical devices?

A Yes. Actually, the first presentation I ever made at a
09:13:05 professional meeting was an FDA organized meeting, it was on safety of blood pressure medicines in the elderly and whether or not they had more side effects than younger people. Turns out they do, but they take their medicines better than younger people.

09:13:19 But that was -- my involvement with studies of safety and side effects goes all the way back to the start of my career.

Q In this case you were retained by my law firm to consult and provide an expert opinion; right?

09:13:33 A Yes, that's right.

Q What were you asked to do?

A Well, the issue came up, and this started back in late 2010, about what was the state of knowledge in the medical literature of -- about the known complications and safety
09:13:48 issues and the benefits of inferior vena cava filters.

09:13:52 Specifically the Bard family of filters. So they asked me if I would just do a systematic analysis of all of the studies. What do they show, what do physicians and others know from reading the medical literature.

09:14:05 Q So to break that down a little bit, you were asked to go back and review an extensive amount of medical literature? That was step one?

A That's correct. There's about 2,000 papers on inferior vena cava filters of various kinds, and a small fraction of

09:14:20 those are actual studies. But there's quite a bit published about them.

Q Okay. And have you formed an expert opinion as an epidemiologist based on your review of medical literature?

A I have.

09:14:36 Q Okay. And are those opinions that you had formed, formed to a reasonable degree of scientific certainty as a medical doctor and an epidemiologist?

A Yes, they are.

Q Okay. Before we start talking about your studies, in your

09:14:47 medical practice have you ever implanted an IVC filter?

A No, I've not. Actually, one of my research areas of interest was pulmonary emboli, and I had patients that I referred to others to implant those. In those days it was the Greenfield filter. So, but -- so I have experience in

09:15:04 considering the risks and benefits and recommending the use in

09:15:08 certain patients. But it was back in the 1990s, so quite a time ago.

Q Does your lack of experience in actually implanting or retrieving a filter inhibit your ability to evaluate the 09:15:21 sufficiency of the information in the medical literature you reviewed?

A No, not at all.

Q And the purpose of the review of that medical literature was what?

09:15:32 A Well, one of the questions was whether or not there is -- there are the type of studies you can actually be very quantitative about exactly what the risks for certain types of problems that are common to almost all filters, such as migration or fracture. And there has been quite a good deal 09:15:53 written about that.

But the devil is in the details in terms of the methodology about whether you can be quantitative about it or whether or not you simply have a collection of studies that describe these things but don't really -- don't really give 09:16:05 you a ballpark understanding of how often they occur.

Q We've talked about you were retained by my law firm. And are you being compensated for the time that you spent evaluating the studies to determine whether a rate could be determined?

09:16:20 A Yes, I am.

09:16:21 Q And how much do you charge per hour?
A I charge $650 per hour.
Q And does your rate change whether you're researching and reviewing medical literature or whether you're here today
09:16:30 testifying?
A No.
Q Okay. And you talked about that you have been doing this analysis of medical literature for quite a while. How much have you billed in connection with this long-term study of
09:16:43 medical literature of IVC filters?
A I think I first invoiced for work relating to this in 2011, and since then, you know, estimating through charges for today, approximately $230,000.
Q Let's talk about some of the types of medical literature
09:17:04 that you reviewed in doing your work. Can you tell us generally what it was and the body of materials you looked at.
A Sure.

Well, as you might imagine, some studies are better than others. And so epidemiologists and even clinicians think
09:17:20 of them as a kind of a hierarchy. There's certain things you look for first.

So the first thing you look for is to see did anybody ever do a randomized control trial. Anybody ever recruit a bunch of patients and say, we can either put in a Bard filter
09:17:34 or we could treat you with drugs or we can treat with you

09:17:36 nothing. Did anybody ever do a randomized study like that.

So I looked for randomized control trials, and there aren't any.

And then, after that, we have observational studies. 09:17:48 And some of those are very well organized and they follow patients from the time of an implant and systematically evaluate the implant by doing X-rays and follow-up exams. And sometimes it's just one implant, sometimes they may be comparing two implants, and those are typically called cohort 09:18:10 studies; you're following these two cohorts along and seeing what happens.

Then there's case series where you have a bunch of cases but you're not really sure where they relate to. There are case reports, which are just single one-off reports of 09:18:26 someone saying this is what happened. Those are often the unusual things.

And then there are people trying this retrospectively. They'll say, well, let's take all the patients who came in to have their filters removed and see 09:18:39 what's going on with their filters. And so there's studies like that.

So there's different types of studies. You learn different things from them. But there are very few studies that actually were designed to actually find out what 09:18:52 proportion of patients developed certain complications,

09:18:54 because they didn't have the whole population. Those are best done if you start at the beginning and go forward. And there aren't very many of those.

Q Okay. You've talked about a variety of types of studies, 09:19:04 and you mentioned a randomized control trial. Would you -- for reliability purposes to determine reliable rates for adverse events, how would you describe the randomized control trial?

A That is the gold standard because you start with a group 09:19:23 of people, and then you let a computer do it. You basically flip a coin, so you don't know who is going to what group. So by the time you have groups of any size, they're really very similar.

And then the only thing that differs is one thing, 09:19:37 the intervention. And then you follow that over time. So because of that, you can actually very reliably make a direct comparison between those in the patients that are studied.

Q In your review of the medical literature for IVC filters dating back to 2010, when you started your review, but in your 09:19:57 review of the medical literature, has there ever been a randomized control trial for any IVC filter?

A No. There has not been. And it's in part because usually if someone needs a filter it's because they can't take drugs. So you can't say, well, we're going to give you drugs anyway.

09:20:17 MR. LOPEZ: Objection. First of all, beyond the

09:20:18 scope of the question, and I don't think what he's talking about now is in his report.

THE COURT: Well, you said beyond the scope of the question. Did you mean --

09:20:26 MR. LOPEZ: It was beyond the scope of the question.

THE COURT: The question? You don't have that objection. The questioner does.

MR. LOPEZ: I'm sorry, Your Honor?

THE COURT: You said beyond the scope of the

09:20:35 question.

MR. LOPEZ: In other words, she asked a question --

THE COURT: You can't make that objection. Only the questioner has that objection. So overruled.

MR. LOPEZ: I'm objecting that his answer went beyond

09:20:48 the scope of the question, number one.

THE COURT: Okay. That's overruled.

MR. LOPEZ: Not in his report that he's about to talk about right now.

THE COURT: All right. That's a relevant objection.

09:20:57 MS. HELM: Your Honor, I would refer the Court to his prior testimony, page 1951, lines 8 to 15.

THE COURT: I don't have any copy of that.

MS. HELM: Yes, you do -- I'm sorry, Your Honor.

THE COURT: Not at page 1951. It starts on page 67

09:21:20 and goes to page 93.

09:21:23 MS. HELM: Your Honor, it's on page 85, page number at the bottom, and then midway through the page it says 1951 on the right.

THE COURT: All right.

09:21:40 MR. LOPEZ: I'm sorry, Counsel, what line?

THE COURT: Page 85, Mr. Lopez, bottom half.

MR. LOPEZ: I'm at 1951.

MS. HELM: Lines 8 through 15.

THE COURT: Would you show Mr. Lopez where it is,

09:21:56 please.

MS. HELM: Sure.

MR. LOPEZ: You said 1951; right?

THE COURT: Mr. Lopez, do you stand on that objection?

09:22:24 MR. LOPEZ: Again, Your Honor, it wasn't in his report, so, yes, I do.

THE COURT: All right.

Where is it in the report, Ms. Helm?

MS. HELM: Section 2, page 4. Under the category A,

09:22:42 Study Design and Reliability of Evidence, and then Randomized Control Trials.

THE COURT: Okay. Give me just a minute.

I see where he says it hasn't been done, but I don't see an explanation as to why. Is that on page 4 somewhere

09:23:18 or --

09:23:19 MS. HELM: It carries onto page 5 and carries on in his testimony, in his prior testimony as well, Your Honor.

THE COURT: Right. But I think the fact that it was in previous testimony, if it's not in the report, isn't

09:23:31 sufficient, so I'm going to sustain the objection.

MS. HELM: Okay.

BY MS. HELM:

Q Dr. Feigal, you talked about randomized control trials, and then you also talked about different types of trials,

09:23:50 prospective cohort studies, case studies, and retrospective studies. Can you calculate from those types of studies accurate rates of adverse events?

A You would from the prospective cohort studies if you had planned examinations. You can't tell if something's gone on

09:24:12 in this filter unless you get an X-ray of some kind, CT scan or something else.

And so most of the studies actually did not have planned follow-up after the implants. So you don't really have accurate rates. So if the studies had been done you

09:24:27 could do that.

And there are a couple of examples of prospective studies with good follow-up with everybody and planned X-rays. But there are very few of those.

Q And are there any of those from which you could calculate

09:24:41 accurate rates of adverse events for IVC filters?

09:24:46 A No, because typically -- the ones with respect to Bard, they're about a single filter, and they've been relatively short term. Say, for example, six months. And there's been very few adverse events during that time period, so you really 09:25:02 can't calculate rates from what happens after six months. You know during six months, not very much happens.

Q What do you need to be able to calculate rates?

A You need to have complete follow-up of everybody. Because if you start losing people, and there are some studies that 09:25:17 have lost as many as 85 or 90 percent of the patients who were implanted, you don't know what happened to those people. So you need complete follow-up, and you need planned measurements, the same in everybody, that occur so that you can actually look for whether there's been a fracture or a 09:25:34 migration.

Q And in the 2,000 articles and the approximately 100 relevant studies that you have reviewed, have you been able -- have you seen that? Have you been able to find a controlled group and accurately calculate rates of adverse events of IVC 09:25:52 filters?

A No. There isn't any study that's actually been designed to do that.

Q Okay. Now, the jury has heard about a published study known as the Nicholson study that discussed adverse events of 09:26:03 Bard filters. Are you familiar with that study?

09:26:07 A Yes, I am.
Q And is that one of the studies in the medical literature you examined as a part of your investigation in this matter?
A I did.
09:26:12 Q What was that study about?
A What Dr. Nicholson did was that after he had seen a patient who had an unusual complication, he called back patients who had had implants at a hospital in Pennsylvania, York Hospital. And then he used fluoroscopy, a type of X-ray
09:26:28 that's available in the cardiology suite, to look to see what the status of the filters were.
Q And do you agree that that study can accurately analyze adverse event rates for Bard filters?
A No. There's -- there's a large number of problems with
09:26:44 that study. And actually we have quite a bit of detail about that study because during discovery he was deposed and study records are available.
Q And what were the problems with the study?
A Well, the first problem is that -- particularly, if you
09:27:00 look at the study as published, it isn't what it says it was. He said he had all implantations at York Hospital over about a four-and-a-half-year span. Well, in fact, he only had maybe a third of those.
And to make matters worse, he included patients who
09:27:19 were not part of the group he said that should have been

09:27:23 included, which increased the numbers.

He also excluded patients who had had their filters removed who had no fractures or problems. He should have counted those as part of the group that had no fractures.

09:27:36 And he only pursued patients who had their implants done in certain parts of the hospital, and not others.

And then in the paper he said, well, the strength of the study was that there's so many different people putting in filters. But it turned out of the 13 fractures that he

09:27:53 reported, fractures and migrations, ten of them were implanted by a single surgeon. So what he really had was a study that showed that they had a surgeon who probably has the highest rate of complications ever performed. He said, well, he thought it was not -- he thought the strength of the study was

09:28:15 there were so many different people implanting this. But, in fact, if you take --

MR. LOPEZ: Your Honor, I'm going to object. This is not in his report, and he's also testifying on hearsay right now.

09:28:31 MS. HELM: Your Honor, he discusses the Nicholson study at length in pages 11 through 16 of his report. And discusses the -- his criticisms of the report specifically on page 13. In the paragraphs -- it starts on page 12 about limitations to the fact a single physician was associated with

09:29:00 ten of the 13.

09:29:01 THE COURT: Right. I see that.

MR. LOPEZ: My objection is he's quoting Dr. Nicholson. That is hearsay.

THE COURT: Well, that was your second objection.

09:29:10 MR. LOPEZ: Right.

THE COURT: The first is overruled because it's in the report.

What is your response --

MR. LOPEZ: That was the part -- well, I know the 09:29:15 Nicholson study is in the report. It's the part that he's talking about Dr. Nicholson said that's not in his report.

THE COURT: Well, that wording isn't. But clearly the same point is in the report, so I'm overruling what was nondisclosure.

09:29:31 What is your response on hearsay?

MS. HELM: Your Honor, the Nicholson article has been admitted into evidence, and I believe Dr. Feigal can testify about what Dr. Nicholson reported in the article, and that's what he's doing.

09:29:43 THE COURT: Well, he can read from the article under 803(18), but that doesn't allow him to bring in other hearsay from Dr. Nicholson.

MS. HELM: We'll move on, Your Honor.

THE COURT: All right. The objection is sustained.

09:29:54 BY MS. HELM:
Q In your opinion, can the Nicholson study be relied upon for scientifically reliable data of adverse events in IVC filters?
09:30:02 A No, it can't. And Dr. Nicholson published a correction to his paper where he pointed out that only three of the fractures had been implanted by a surgeon other than the single surgeon who had the very high rate of complications.
Q Is the Nicholson article still being cited today?
09:30:21 A Unfortunately, it is. Unfortunately, it is. Not all of the limitations of the study were actually brought out in Dr. Nicholson's correction.
Q Okay. And you would agree that there are studies that show there have been adverse events in IVC filters, would you
09:30:39 not?
A Oh, yes. There's one study that cited migration and fracture in 17 different models of filters, including one -- I think, as I recall, nine of which had come from Bard filters. But of the 100 fractures there were 17 different models
09:30:59 involved.
Q But, again, did you find any studies that met all of the requirements that are necessary to determine an accurate rate of adverse events of IVC filters?
A No. What the literature establishes is that these are
09:31:11 known risks of -- we can tell they're low frequency of events

09:31:17 and that they occur across all the models, virtually on models of all of the filters.

Q I want to narrow my question down. Did you find any studies that met the requirements that are necessary to

09:31:27 determine an accurate rate for adverse events for Bard IVC filters?

A No.

Q And let me narrow it down a little further. Did you find any studies that meet the requirements that are necessary to

09:31:40 determine an accurate rate for adverse events in the Bard Eclipse filter?

A No.

MS. HELM: No further questions.

THE COURT: Cross-examination?

09:31:52 MR. LOPEZ: Thank you, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. LOPEZ:

Q Morning, Dr. Feigal.

A Good morning.

09:32:11 Q I just want to make sure this is clear. In 2010 you said you did a systematic study of the medical literature. You did that on behalf of lawyers that have hired you to do that; correct?

A Yes. That's the reason I did it.

09:32:24 Q So it wasn't Bard that came to you and said we have a

09:32:27 problem that we're looking into, we'd like to hire you to look at the medical literature for us to more fully understand what's going on with our product? It was lawyers that hired you to do that; correct?

09:32:37 A That's correct. That was where I was retained by lawyers for Bard.

Q You said for the past 20 years -- let me ask you, for the past 20 years have you treated patients?

A I stopped seeing patients in 1992. So that's the last

09:32:56 time I saw a patient.

Q All right. And so have you ever evaluated a patient to determine whether or not a patient was a candidate for an IVC filter?

A Not since 1992. Before that, yes.

09:33:08 Q Have you ever looked at the MAUDE database or the medical literature to determine whether or not, if you were going to prescribe or recommend a Bard filter, which filter had the safest profile?

A I'm very familiar with the MAUDE database, but that's not

09:33:25 a database that would tell you which product is safe. It tells you which products had reports. But, no, I wouldn't use the database for that purpose.

Q Do you know that there's evidence in this case that many doctors that were using Bard filters, by looking at data in

09:33:38 the MAUDE database, decided not to use the product anymore for

09:33:42 concern about safety?
A I don't know one way or the other about that.
Q Do you know that there's evidence in this case where hospitals took Bard filters off their formulary after seeing
09:33:53 single reports of complications with Bard filters because of the seriousness of the complaints?
A Again, I have no knowledge about what the hospitals did with the use of which filters.
Q Now, when you left FDA in 2004, did -- your first new
09:34:13 venture was doing litigation expert witness work? Is that true?
A No. I joined a group called NDA Partners, which I'm still a partner in. We're a group of 130 consulting experts. We work with any given time over 100 companies, usually startups
09:34:34 developing medical products.
Q Okay. Now, in 2014, when you testified under oath regarding Bard filters, you said that 40 percent of your income was derived from litigation. Is that still the percentage? Is it higher or lower than that now?
09:34:54 A That was correct for 2014, where there was an unusual drug case that had ten trials in one year. But year in, year out, my average percentage of my income from litigation is 25 percent of my income.
Q And as of at least 2014, 95 percent of the time when you
09:35:10 were asked to be an expert in a pharmaceutical or drug device

09:35:17 case, it was on behalf of a manufacturer. True?
A It was true at that time. Actually, I've had more plaintiffs' work since that time and have done depositions for plaintiffs, attorneys representing plaintiffs.
09:35:30 Q In medical device cases?
A Yes, in medical device cases.
Q What other medical device case?
A I've offered testimony in a case involving surgical equipment called a morcellator on behalf of attorneys for the
09:35:42 plaintiffs of a patient who died from complications.
Q Now, sir, again, this is going back to 2014, because you and I haven't spoken since then. True?
A That's correct.
Q And you had 15 to 20 appearances on behalf of medical
09:35:57 device companies as of that date where you were an expert witness defending them. True?
A Well, not actually asked to defend them. I'm actually asked to provide expert opinions typically about epidemiology or sometimes other topics. But, as you pointed out, the
09:36:11 majority of the people who have asked me to testify have been manufacturers.
Q Okay. And, again, this is in 2014, you were an expert on behalf of a company called Roche, who manufactured and sold a drug called Accutane that caused birth defects. True?
09:36:32 A Yes. But I was not retained for cases for birth defects.

09:36:36 Q And as of 2014 you had made approximately $250,000 defending Roche; right?
A Not defending Roche, but offering testimony on the risk, and in this case it was an inflammatory bowel disease
09:36:47 associated with Accutane, the acne medication.
Q Can you give us your best estimate, sir, over the last number of years you've been doing expert witness work, that you've made in working for either drug or medical device companies?
09:37:07 A You know, I don't have an exact figure, but I would say approximately 25 percent of my income comes from work relating to litigation. The majority of that is for manufacturers. And my average income over the last ten, 15 years has been about $600,000 per year. So about a quarter of that since
09:37:24 2004.
Q So I can't do that math, but it sounds like somewhere between 2.5- and $3 million?
A I'm not sure I can do the math either, but that --
Q That sounds about right?
09:37:34 A That sounds about right.
Q Now, do you know Susan Alpert?
A I do.
Q And you know Susan Alpert left FDA and went to work for Bard?
09:37:43 A She did, yes.

09:37:44 Q And she was the medical director of Safety and then the Office of Device Evaluation at FDA?

A She was. That's the same position that Donna-Bea Tillman held, yes.

09:37:56 Q And when she went to work for Bard, do you know what role she played in assisting Bard to get clearance of their first retrievable IVC filter?

A I don't. No.

Q Do you know Donna-Bea Tillman?

09:38:07 A Yes.

Q And was she at FDA when you were there?

A Yes. She reported to me or reported to me through another person.

Q And you know that Donna-Bea Tillman is -- signature

09:38:16 appears on one of the clearance letters that we're talking about in this case.

A I haven't seen that letter, but that wouldn't surprise me.

Q Now, if you're going to get data to see if your device is actually performing safely and effectively, instead of just

09:38:31 waiting for reports to come in that might or might not come in from the real world, from voluntary reporting, I think you listed a number of things that a company could have done. For example, you mentioned that there were two trials that the company had done but they -- after a certain period of time

09:38:50 they decided they weren't going to follow those patients to

09:38:53 see how they did with those devices still in them over time.
Do you remember saying that?
MS. HELM: Your Honor, I object. It exceeds the scope of the direct.
09:39:01 THE COURT: Hold on just a minute.
I think you need to reask the question, if you would, please, Mr. Lopez.
MR. LOPEZ: All right.
BY MR. LOPEZ:
09:39:27 Q I wrote this down. You said most studies as they relate to Bard filters did not have planned follow-up with planned X-rays. Do you recall that?
A Yes. I mean that's not -- that's true not only of the Bard studies, but it's -- it's -- most of the -- most of the
09:39:42 medical literature did not ask patients to come in and get follow-up X-rays.
Q I'm just going to talk about the two Bard studies. There was the Asch study where they got certain data regarding risks and complications, but Bard did not follow patients beyond a
09:40:00 certain time period to see how those patients were going to do from the standpoint of complications after they were released from the study. True?
A Well, that's --
Q Is that true?
09:40:11 A That is correct.

09:40:11 Q Okay. And the same with the Eclipse study. After 180 days there were a number of patients who continued to have the device and Bard decided not to do planned follow-up with planned X-rays to see how the device was going to perform 09:40:25 after six months. True?

MS. HELM: Your Honor, I do object and ask Mr. Lopez to correct the record. He referred to an Eclipse study.

MR. LOPEZ: I'm sorry. You're right. I did. Thank you. I should have been saying EVEREST study. I do that all the time, by the way. I mix those two up. Let me start over. 09:40:40 BY MR. LOPEZ:

Q The EVEREST study then involved the G2 did not have planned follow-up with planned X-rays for patients beyond 180 days. True?

09:40:52 A That's correct. It was a retrievability study, so they went to the time when they were going to retrieve them and they retrieved a large number of them, and that was what the study was planned to do.

Q Now, unfortunately, based on what you just testified to, 09:41:04 the best data that we have regarding the safe performance or the potential risk of this device is the route that Bard shows, and that is let's see what happens in the open marketplace and hope that physicians report complications to us. True?

09:41:23 A That was part, but not all. Because there also was an

09:41:26 extensive medical literature which is separate and above and beyond the reports to the company.

Q Okay. So in addition to waiting to see if doctors report to Bard that they may have a complication that they're

09:41:41 concerned about, Bard decided let's waited and see if someone like Dr. Nicholson wakes up five years later, decides to do a retrospective study to see if there are problems with fractures and what happens when patients have fractures. That's the other thing that Bard decided to do?

09:41:57 A I have no information about Bard and what they decided to do.

Q Yeah, but you just said that or they can wait for medical literature, I think, they can see what's in the medical literature; right?

09:42:06 A They didn't need to wait. The medical literature has been developing on inferior vena cavas ever since the Greenfield filter, so this is on ongoing area. And you have the professional societies offering guidance and commentary, so it's an area where there is very active discussion of the

09:42:22 risks and benefits of these products --

Q But do you understand this is about Bard products. It's not about just generically IVC filter products. We're talking about the performance of Bard products that are on the market. You understand that?

09:42:34 A Yes.

09:42:35 Q And the truth is Bard never sponsored someone like Dr. Nicholson or Dr. Vijay, whose article we saw: Why don't you take a look at your hospital records going back four, five years, and see how much fractures we have. They didn't do 09:42:48 that, did they?

A Um --

Q Did they do that?

A Bard -- I don't know what -- I do not have -- I have not reviewed Bard documents.

09:42:56 Q And, sir, I'd like --

A But Bard did not sponsor those studies.

Q And so I think one thing we can agree you on, you can't use adverse events to determine rates and you can't use medical literature to determine rates. True?

09:43:07 A You can't use this medical literature and you cannot use adverse events, yes. I would agree with you.

Q Would you agree with me that it would be false and misleading if a company or anyone speaking on behalf of -- on its behalf were to use AER data to affirmatively state that 09:43:24 our failure or complication rates are X?

A I would have to see the specific. I -- it would depend on what they said and what that's based on. I can't answer that as a hypothetical.

Q Well, let's just say they said that our failure rate is 09:43:40 less than 1 percent, and they based that -- and they want the

09:43:42 world to believe that is their failure rate, and that is based on adverse event reporting. That would be false and misleading to suggest that is their failure rate. True?

A Not necessarily.

09:43:52 Q Would that be false and misleading? Yes or no?

A Not necessarily.

Q Okay. Now, one of the primary reasons companies cannot use adverse events to state this is our failure or complication rate is because you don't know whether there were

09:44:04 ten or 100 times that this same event happened in other patients where it was not reported. True?

A That's correct.

Q And what a response -- what an ethical company should do in the interest of patient safety is assume you might be just

09:44:20 seeing the tip of the iceberg when you get these reports; right?

A No, I don't think they should do that either. They should --

Q Okay. All right. Then, in a situation where there is

09:44:28 underreporting, we have, number one, where doctors find out there is a problem and they choose not to report it, right, because they don't have to?

A That's correct.

Q And, but, in a situation where you have a number of

09:44:38 patients where doctors don't know because the patient doesn't

09:44:41 know that they actually have this problem, that's another thing that contributes to underreporting. True?

A That's correct.

Q In other words, if it's known that these devices could

09:44:54 actually break and they actually could embolize to a distant organ, but a patient doesn't know about it, he's not going to report it to his or her doctor; correct?

A That's correct.

Q And that's another reason why there might be significant

09:45:06 underreporting of adverse events as they relate to a filter like Bard's. True?

A That's right. Because there's no adverse events.

Q Were you aware that Bard's medical director, Dr. Ciavarella, testified that they are likely getting only 1

09:45:24 to 5 percent of what is really happening in the open marketplace?

A I haven't seen his testimony.

Q Okay. Now, again, assuming you have -- listen to this question, please, very carefully. If you've sold 100 Bard

09:45:32 filters -- this is a hypothetical -- and among those 100 you get one report of a serious injury or death, do you follow me so far?

Sir?

A Yes.

09:45:41 Q And wouldn't it be misleading for someone to say that the

09:45:44 unreported cases are evidence of a 99 percent success rate? Yes or no?

A Well, I can't answer that yes or no.

Q Well, you --

09:45:53 MR. LOPEZ: Can I have his testimony, Gay, please, from 2014, page 80, lines 3 to 17.

BY MR. LOPEZ:

Q Sir, you remember you gave sworn testimony in 2014? See that?

09:46:16 A Yes.

Q And the question was that: "We don't know anything else about the other 99. Nothing. We don't know whether the device has ever been challenged by a clot, we don't know whether the doctors put it in for a short time and it's been

09:46:28 taken out, we don't know whether it's moved up or down a centimeter or whether there's a fracture. We know nothing about the other 99. Do you follow me so far?"

"Answer: Yes."

"Do you think it would be a little misleading if

09:46:41 someone were to say that the other -- that the data proves that 99 percent of the time our device does not migrate?"

"I think if that was the data based on reports I think -- that would be misleading."

You testified to that in 2014, sir?

09:46:57 A That's a different question than you asked me, but yes, I

09:47:00 stand by that testimony.
Q You have stated in prior sworn testimony that adverse event data is not a data source that predicts rates of success any better than it predicts rates of complications. True?
09:47:13 A You cannot get rates either for success or failure, with the exception of deaths, where there is mandatory reporting from health facilities.
Q And -- I'm sorry.
A With a death there is mandatory reporting to FDA from
09:47:26 health facilities, and they lose their accreditation if they don't report those. So there is good data on deaths. But the rest of it, you're quite right, it's voluntary.
Q And isn't the bottom line that there are defects in using MAUDE data and there are defects in reports in the medical
09:47:40 literature data?
A I don't know what you mean by defects.
Q In other words, you can't really know what the rate is by looking at either one; right?
A Well, you could -- not from MAUDE, but from literature,
09:47:49 you could hear or you can put some bounds on it from what's been reported. But there haven't been studies done that get the rates. That's what I testified to.
Q And you should not be making representations about rates of complications comparing AER data with medical literature
09:48:04 data. Do you agree with that?

09:48:06 A Depends on the representation. I'd have to see what you're talking about to be able to answer that question.
Q In other words, Bard says, well, our complication rate is less than 1 percent, and they're basing that on adverse event
09:48:19 data, and then they're taking a piece of medical literature that says that the rate is 2 percent or -- or also less than 1 percent. You can't do that; right? And say that these two things are comparable because you compared one to the other?
A Well, I think you've asked me several questions there.
09:48:37 Q I'm running -- I just got a note that I need to hurry.
Question: The reason you look for a safety signal is once it's on the market, especially if there's no long-term clinical trials for safety is to find out whether or not something unexpected and unintended is happening with your
09:48:55 product so you can take steps to protect people from those risks. True?
A Yes.
Q And AERs give the company the first hint that they may have a design issue with their product. True?
09:49:06 A Sometimes, but not always.
Q Well, sir, I can show you the testimony. You just gave me a yes last time. Is that a true statement?
A It's often true, yes. Not always, but yes.
Q And haven't you made public statements that, quote, there
09:49:17 are times a single case can identify a design issue?

09:49:21 A Yes. If it's something novel that hasn't been seen before.

Q Okay. Now -- so let me ask you, if a single case can do that, what if you have 13 cases of the same device failure 09:49:31 within the first six months of a device being on the market. Would that be stronger evidence of a design issue than just one report?

Sir, can you answer that yes or no?

A No, I can't answer that yes or no.

09:49:44 Q And you were not provided with documentation by Bard or its lawyers on the adverse events and the company's risk analysis that concluded the G2 filter posed an unacceptable risk of serious harm to patients. True?

A It's true I did not review the Bard documents.

09:50:01 THE COURT: Excuse me, Mr. Lopez, let him answer.

MR. LOPEZ: I'm trying, Your Honor.

BY MR. LOPEZ:

Q Sir, if you could just answer --

THE COURT: Just let him finish his answer.

09:50:08 MR. LOPEZ: I will.

BY MR. LOPEZ:

Q And you were not provided with documentation that based on that analysis that whoever did the analysis -- not whoever did the analysis but the actual policy of Bard was that they 09:50:19 should not launch the product into the open market until they

09:50:22 fix the problem. You weren't given that information; right?
A I was not asked to review to Bard documents, no.
Q And you were not advised that that analysis was done based on the reports they were getting voluntarily from doctors in
09:50:36 the first six months the device was in the market. True?
A I don't know.
Q You were not shown Bard internal documents discussing design deficiencies that explain these early events?
A No. It was outside the scope of what I was asked to do.
09:50:51 Q And were you provided with documentation that the medical director stated that doctors should be using the Simon Nitinol filter and not the G2 because of the comparative history of adverse events that were being reported to the company? Were you advised of that?
09:51:06 A Again, I didn't review any Bard documents.
Q Sir, you've written in open medical literature concern that corporate culture and their financial bottom line adversely influences companies to not focus on product performance and patient safety. True?
09:51:21 A I don't know if that is a direct quote. That is sometimes true, but it's generally not true. It is bad business to not take care of patient safety.
MR. LOPEZ: Exhibit 1212 please.
BY MR. LOPEZ:
09:51:30 Q Sir, do you recognize this article?

09:51:34 A Yes.
Q And you wrote this -- you were an author on this article with Dr. Myerburg. True?
A Yes.
09:51:40 Q 2006; correct?
A Yes.
Q And have you written any articles on the subject matter of medical devices or pharmaceuticals since 2006?
A I don't recall. I may have, but I don't recall.
09:51:56 Q Would you please look at the third page of this exhibit -- and, by the way, the title of this is -- and this was published in the New England Journal of Medicine; right?
A That's correct.
Q And it's about the most prestigious journal that exists in
09:52:10 maybe the world, but for sure in the United States; right?
A I would think so. I read five or six publications there.
Q And you wrote this article for other physicians to look at and read and rely upon for purpose of your opinions and your perspective as a former FDA person; right?
09:52:27 A That's correct. But it was on behalf of a panel that was actually commissioned by Guidant to evaluate a safety problem they had with a pacemaker that occurred one in 25,000 patients.
Q And, sir, on page 2311 -- you see where I am? Middle
09:52:42 paragraph, see where it is highlighted?

09:52:46 You wrote: "Voluntary independent review of the level suggested is a notion both foreign and frightening to most corporations, whose perceived need is to protect business interests. But corporate culture fosters a loyalty to 09:53:05 corporate goals that may create unintended bias and distorted perceptions about product performance and patient safety."

You wrote that in 2006; right?

A I --

Q Did you write that in 2006?

09:53:19 A I or my co-author.

Q Have you retracted this article since 2006?

A No.

Q And you wrote that after having a perspective of having worked with pharmaceutical and drug companies not only as a 09:53:30 officer at FDA, but as a consultant to corporations after you left FDA. True?

A That's right. This article was about Guidant Corporation.

Q When a company gets safety signals their focus should be on reducing or eliminating the risk being reported and not on 09:53:48 market share or sales goals. True?

A Yes. And most companies do that.

Q Dr. Feigal, should the sense of patient safety and public health be different for the American consuming public getting a Bard filter than someone that was in a clinical trial 09:54:03 involving the same product?

09:54:06 A No. I mean, safety's safety. You're always concerned about that.

Q When a drug or device is new, companies like Bard need to be very cautious once it gets into widespread use. True?

09:54:17 A Yes, if it's very novel, if it's not related to other products which have experience you can rely on.

Q And when they see things reported they were not expecting, predicting, or representing to FDA and doctors, they need to stop and take whatever steps necessary to avoid future harm to

09:54:32 patients. True?

A Yes, if they saw something that wasn't a feature of the filters, but I don't think that was the case.

MR. LOPEZ: Those are all the questions I have, Your Honor. Thank you.

09:54:45 THE COURT: All right. Redirect.

MS. HELM: Yes, Your Honor.

R E D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Dr. Feigal, Mr. Lopez just talked to you a lot about what

09:54:53 you were not shown and what did you not know.

Would you again tell the ladies and gentlemen of the jury what you were asked to do in this case.

A So what I was asked to do was to assess the state of the medical literature for complications from inferior vena cava

09:55:08 filters to assess whether or not things like fracture and

migration and embolization were well recognized for all filters, and for Bard filters in particular. And whether there was any -- any studies of the hundreds or so papers that reported clinical data, direct clinical data, that allowed you to actually calculate a rate so you could be quantitative about that risk, not just know, as has been known about all filters, that they can fracture and that they can embolize and they can migrate.

Q Were you asked to evaluate Bard's internal analysis of adverse events?

A No. Only in one small part as it related to the MAUDE, since that was in the literature as well.

Q Have you seen Bard's internal analysis of adverse events reported to Bard for any of its filters?

A No, I've not.

Q And you've not been asked to evaluate that because you haven't seen it; right?

A That's -- that's correct.

Q So you were asked a lot of hypothetical questions, shouldn't a company do, shouldn't a company do. You can't answer those about whether Bard complied with the "shouldn't theys," because you haven't seen their internal analysis or how they reacted to adverse events?

A That's correct.

Q Okay.

09:56:22 But you would agree that a company should analyze adverse events that are reported to the company?

A Yes, they should.

Q And in this scenario, you just haven't seen appropriate 09:56:36 information in the medical literature to calculate rates of adverse events for IVC filters; right?

A That's correct.

Q At the beginning of your testimony, Mr. Lopez asked you about the fact that you serve as a consultant and work in what 09:56:51 we call the medical legal field. Do you remember those questions?

A Yes.

Q Does the fact that you derive part of your income as a consultant in the medicolegal field, did that impact your 09:57:05 opinions in this case?

A No. I mean, I view my role to be an expert that is intended to help the jury understand the technical issues, such as how to evaluate certain different types of studies, in this case, and what you can learn from them and what you 09:57:18 can't.

Q Does the fact you serve as a consultant in the medical field, often on behalf of either drug or medical device manufacturers, does that in any way impact your opinion as to whether the medical literature available to doctors, to 09:57:34 medical device companies, is sufficient to calculate a rate of

09:57:39 the risks of adverse events of IVC filters?

A No.

MS. HELM: That's all I have. Thank you.

THE COURT: All right.

09:57:48 Thank you, sir. You can step down.

If you want to stand up, ladies and gentlemen, while we get the next witness in, feel free.

We're trying to cool off the courtroom for those of you who feel warm.

09:58:09 Sorry, Mr. Rogers.

MR. ROGERS: Your Honor, I was going to inform the Court that we're going to call the next witness for the defense, Dr. Christopher Morris.

THE COURT: All right.

09:58:18 THE COURTROOM DEPUTY: Dr. Morris, if you would please come forward and raise your right hand, sir.

CHRISTOPHER MORRIS, M.D.,

called as a witness herein, after having been sworn or affirmed, was examined and testified as follows:

THE COURTROOM DEPUTY: Would you please state and spell your name for the record, sir.

THE WITNESS: Christopher Scott Morris.

MR. ROGERS: Your Honor, may I approach with some materials related to Dr. Morris?

09:58:51 THE COURT: Yes.

09:58:58 MR. ROGERS: Your Honor, would it be okay if I move the easel?

D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

09:59:21 Q Good morning, Dr. Morris.

A Good morning.

Q Can you introduce yourself to the jury, please.

A My name is Christopher Scott Morris, and I'm an interventional radiologist.

09:59:31 Q Where do you live and work?

A I live in Vermont and I work at the Lerner College of Medicine at the University of Vermont, also known as University of Vermont Medical Center.

Q What city is that in Vermont?

09:59:45 A Burlington, Vermont.

Q And, Doctor, can you give us a little bit of detail about your educational background, please.

A Yes. I went to medical school in Cleveland at Case Western Reserve University School of Medicine, and then I did

10:00:00 an internship in Cleveland at the same institution. Then I did my diagnostic radiology residency in Columbus, Ohio, at Ohio State University. And after that I did a fellowship in interventional radiology at Mass General Hospital in Boston. And ever since then I've been at the University of Vermont.

10:00:21 Q In addition to your degrees in medicine, do you also have

10:00:25 a master of science?
A Yes, I do.
Q And tell us about that, please. What's that in?
A That was also obtained at Ohio State, and that's in
10:00:35 radiological sciences and it was mainly focusing on
radiobiology and radiation physics.
Q Dr. Morris, about how many years have you been practicing
as an interventional radiologist?
A I've been at University of Vermont about 27 years.
10:00:53 Q Are you licensed to practice medicine?
A Yes.
Q In what states, please?
A Vermont, California, and New York.
Q And do you have current licenses in those states?
10:01:03 A Yes.
Q And, Doctor, are you board-certified?
A Yes.
Q Have you done any teaching in the area of interventional
radiology?
10:01:11 A Yes. My whole career I've performed teaching, yes.
Q So tell us about that.
A So we have a residency program at our institution where we
train residents in diagnostic radiology. We also have a
fellowship program in interventional radiology, and that is a
10:01:31 pretty intensive teaching requirement that I'm involved with.

10:01:34 So we have two fellows every year that spend every day with me and as well as with my other three colleagues.

We also teach residents and medical students that are on other services, for instance surgery residents. And we 10:01:53 have a clerkship from the medical school so that medical students rotate with us on a monthly basis. So there's lots of teaching activities that occur.

Q Are you a member of any professional societies that relate to interventional radiology?

10:02:08 A Yes. The main one is Society of Interventional Radiology.

Q And are you a member of other professional societies that relate to radiology?

A Yes. Radiological Society of North American, American College of Radiology, American Heart Association. Those are 10:02:24 the main ones.

Q Are you a senior fellow in the Society of Interventional Radiology?

A Yes, I am.

Q Have you done anything in your career where you were 10:02:36 instructing other interventional radiologists at meetings of the SIRs regarding IVC filters?

A Yes. For about six years I've participated in the IVC filter workshop series at the annual Society of Interventional Radiology national meeting, and three of those years I was the 10:02:55 workshop coordinator, so I ran the workshop series during

those meetings.

Q Are you currently involved in a clinical practice?

A Yes.

Q And so tell us about that. What types of things do you do?

A As interventional radiologists, we perform many different types of procedures. I think there's over 100 discrete types of procedures that we perform. It's based on imaged guidance. So we are radiologists, but we're specialized radiologists that do actual therapeutic type procedures. We don't use radiation to perform the procedure, but we use imaging, ultrasound, fluoroscopy, which is a radiology type of imaging system, CAT scans, to perform procedures such as drainages. If someone has a blocked kidney, we'll put a tube in their blocked kidney to relieve the obstruction, for instance. We do that in all the organ systems throughout the body.

And then the other part of our practice is in vascular, so we do a lot of procedures, diagnostic as well as interventional procedures, in the vascular system, such as angioplasty, stents, and IVC filters.

Q When were you first exposed to IVC filters?

A When I was a resident at Ohio State.

Q And have you been consistently utilizing IVC filters in your medical practice since that time?

A Ever since then, yes.

10:04:26 Q And are you still treating patients today with IVC filters?
A Yes, I am.
Q Doctor, when's the last time you placed an IVC filter in a
10:04:35 patient?
A Several weeks ago.
Q And how about when is the last time you would have retrieved a retrievable filter?
A Maybe three or four weeks ago.
10:04:42 Q Have you published any medical literature that relates to IVC filters?
A Yes.
Q And can you tell us about that, please.
A I have -- ever since I've been at University of Vermont,
10:04:54 IVC filters has been a big part of our practice, and early on after the first year I was there, we started a project with the trauma surgeons on IVC filters and their use in trauma patients. So that was one of the first studies that we published relating to trauma patients. There was a follow-up
10:05:16 study on that five years later.

And then we published our experience with the first retrievable filters, called the Cook Tulip filter, in the early 2000s. And most recently we've published our experience using a multidisciplinary clinic to follow-up our IVC filter
10:05:40 patients, and we started that in 2006. And that was

published, I think, in 2017, that five-year intervention that we performed on them.

Q Doctor, have you been retained as a expert witness in this case?

A Yes.

Q And are you charging for the time that you spend in your work in this matter?

A Yes.

Q And what is your customary charge?

A It's a flat fee of $500 per hour.

Q And is that for any activities that you engage in?

A Yes.

Q And prior to becoming an expert witness in the area of IVC filters, have you had any sort of relationship with C.R. Bard where were where you were paid for by C.R. Bard?

A For a few years when retrievable filters came out, so this was in the early 2000s to about 2006 or so, I was a paid consultant for Bard, yes.

Q And what types of things would you have done as a consultant at that time?

A There are basically three different activities. One was I was a monitor, what they call a clinical monitor. So I went to -- actually, just twice to a regional hospital, University of Albany, to teach the interventional radiologists there how to take out the Bard Recovery filter.

10:06:54 And I did the same thing at -- in Schenectady, New York, at a hospital called, I believe, St. Peter's.

And the other activity was that I delivered a few lectures at regional meetings, what we call angio clubs, 10:07:14 around that same time, where I just talked about IVC filters in general. This was the time frame when the retrievable filters were just coming out and a lot of interventional radiologists had not had an experience with those.

And then the third activity I did with Bard was I 10:07:30 participated in a series of focus groups where I think I went to Chicago, Tempe, Arizona, and Memphis, Tennessee, to discuss IVC filters in general with other interventional radiologists during those meetings.

Q And has all that work that you just described, has that 10:07:52 been more than ten years ago?

A Yes.

Q Doctor, let me turn your attention to your opinions in this case. Are you prepared to offer the opinions that you've formed regarding Bard IVC filters?

10:08:04 A Yes, I am.

Q And before we get there, let me ask you this: Are you going to be offering any opinions today that are specific to Mrs. Jones, the plaintiff in the case, or any of her medical care?

10:08:17 A No.

10:08:19 Q Have you reviewed any medical records or imaging that relate to Mrs. Jones?

A No.

Q So, Doctor, what are the opinions that you will be
10:08:27 offering in this case today?

A That pulmonary embolism is a common and very often a lethal disease, and that doctors should strive to decrease the PE mortality rate. That IVC filters are effective in decreasing lethal pulmonary embolism. But that is restricted,
10:08:55 and I want to be very clear about this, in patients that have documented acute venothromboembolic disease, that is proximal DVT of their legs or an acute pulmonary embolism, and in those patients that can't be treated with anticoagulation.

Now, another opinion is that interventional
10:09:15 radiologists are very aware of the complications associated with IVC filters, including tilt, perforation, penetration, migration, fracture, fracture embolization and thrombosis.

And then finally, the family of Bard retrievable filters, IVC filters, including the Eclipse filter, are safe
10:09:40 and effective.

Q Thank you, Doctor.

Let's start off with the first one of those opinions that you said that you would provide regarding the treatment of PE or the prevention of PE.

10:09:55 Over the course of your career, have you treated

10:09:58 patients who had got DVTs?
A Yes.
Q And have you also treated patients who have experienced pulmonary embolism?
10:10:05 A Yes.
Q And, Doctor, can you tell us, where do the blood clots typically originate that may develop into a pulmonary embolism?
A They typically begin within the deep veins of the legs or
10:10:20 pelvis, and once the clot forms, the advancing edge of the clot becomes -- because the new clot is pretty fragile and very delicate, and that's the part of the clot that's at risk of breaking off and then traveling to the lungs and causing a pulmonary embolism.
10:10:39 Q And over the course of your career, have you had patients who have died from a pulmonary embolism?
A Yes.
Q And have you had patients that you're aware of who have had a IVC filter in place who have died from a pulmonary
10:10:51 embolism?
A I have -- I'm not aware of any patient at our medical center that died with an IVC filter in place.
Q And --
A I'm sorry. From pulmonary embolism.
10:11:03 Q Thank you, Doctor, for that clarification.

10:11:06 Do you consider pulmonary embolism to be a significant health risk in the American population?

A It's a huge health risk, yes.

Q And do you have some numbers that may give us some context for that?

10:11:17 A Well, it's generally thought that pulmonary embolism occurs about 600,000 times a year in the United States, and it depends on which study we look at and a lot of these are autopsy studies of hospital deaths, but the death rate from pulmonary embolism has be been described to occur anywhere from 50,000 to 200,000 per year.

10:11:35 Q And, Doctor, if a patient has got a risk of pulmonary embolism and that goes untreated, do you know the rate of potential mortality for that patient?

A Studies have shown between 26 and 30 percent. That means if a patient has an acute pulmonary embolism, whether it's symptomatic or not, the studies have shown by doing pulmonary angiograms that if it's untreated, they will die 26 to 30 percent of the time.

10:11:55 Q And what are some of the primary risk factors that would expose a patient to a high risk of pulmonary embolism?

10:12:17 A Well, the risk factors are multifold. There are types of risk factors that a patient's born with, sort of a genetic predisposition to developing clots. We call that hypercoagulable state. And some of the names of these genetic

10:12:38

10:12:42 defects cause situations that have names like protein C. Deficiency protein, S deficiency, and Factor Leiden.

Then there are the patients that are -- don't have a predisposition genetically, but have other inciting factors 10:13:02 that make them prone to developing clots. So any time a patient is immobilized, which can cause sluggish blood flow. So that can be recovering from surgery, that could be a trauma patient that's paralyzed and just lying in bed for a long time, or it can be someone in a long plane ride. So, you 10:13:22 know, not getting up and exercising the legs. Their legs.

So immobilization is a big risk factor which causes sluggish blood flow.

Another one is trauma in general, either penetrating or deep blunt trauma.

10:13:40 Others include factors such as hormone replacement therapy, and pregnancy is another potential risk factor. And then cancer. Whether diagnosed or undiagnosed, certain cancers have a lot more predisposition to increasing the risks for thrombosis than others, such as anything that interrupts 10:14:05 the blood brain barrier, so brain cancers. And then all of the urologic type cancers also have a real high propensity to increase the risk factors for venous thromboembolism.

Q Doctor, you referred to this a moment ago, but what is typical first line of defense that doctors will pursue if you 10:14:27 have a patient who is at high risk of pulmonary embolism?

10:14:30 A Anticoagulation.
Q And can you explain to the jury what that is.
A So that's basically thinning the blood with medicines. And the first type of medicine that's used is an injectable
10:14:42 medicine called heparin, and that can be either injected straight into the vein through an IV or it can be inserted underneath the skin, a subcutaneous type injection, like an insulin shot.
And then once the patient has stabilized on heparin,
10:14:58 generally speaking, the doctors then will change that medication to an oral pill that they can take. Anticoagulants like Warfarin or the newer direct anticoagulants that are available now like Eliquis or Xarelto, those types of pill, pill-type form.
10:15:17 Q And from time to time do you have patients who cannot take an anticoagulant for some reason?
A Yes.
Q And in those patients, are there any alternative treatments to try to prevent PE other than an IVC filter?
10:15:32 A No.
Q Doctor, do you have an opinion to a reasonable degree of medical certainty as to whether IVC filters are effective in stopping clots?
A I believe they are, yes.
10:15:43 Q And can you tell us what your opinion is based on?

10:15:46 A Well, it's based on a review of the literature, as well as my own personal experience.

Q Why don't we break those down. And let's talk about the literature first.

10:15:57 The jury's just heard some information about different types of studies. And in the worldwide medical literature, are there any studies that would be considered randomized clinically controlled prospective trials that relate to IVC filters?

10:16:15 A There's the PREPIC1 and the PREPIC2 studies.

Q And so what do you mean by that? What is PREPIC1 and PREPIC2? What does that mean?

A So the PREPIC1 was a randomized controlled trial of permanent filters. It was published in 1998, so well before

10:16:31 the advent of the retrievable filters. And there were 400 patients, all of them had proximal DVT. Some of them had PE, but all of them had to have proximal DVT, and they put all those patients, they randomized 400 -- all 400 patients that they enrolled in the study all got anticoagulation. Half of

10:16:53 those, around 200, got a filter, and the other half did not. So right away it doesn't really mimic real world conditions where we place filters in patients that cannot be anticoagulated.

So they looked at the pulmonary embolism rate at 12

10:17:12 days, and then there was an eight-year follow-up study that

10:17:16 they also did. And at that 12 day rate they imaged all the patients, looking for asymptomatic pulmonary embolism. That is very important because we know that there are a lot more asymptomatic pulmonary embolism cases that occur than 10:17:31 symptomatic. So they found that the patients that received the filter had a lower rate of recurrent pulmonary embolism than the patients that did not receive an IVC filter.

However, there was no change in the overall mortality rate between those two groups in the PREPIC1.

10:17:51 So now we flash forward to the PREPIC2 studies done by a different set of authors, but also performed in France. They looked at retrievable filters. It was a little bit different type of a study in that these patients all presented with -- and there were about 400 of them, they presented with 10:18:12 symptomatic pulmonary embolism. Now, they ran -- again, they anticoagulated all the patients. Again, not mimicking real world situations here.

Then they looked at three months and six months at symptomatic pulmonary embolism. They did not do any imaging 10:18:31 unless the patient had a symptom that they thought may be a PE. So they were missing all the asymptomatic pulmonary embolism that could occur.

And in that study, the PREPIC2, with one single retrievable filter, whereas the PREPIC2 had, I think, four or 10:18:47 maybe even five different permanent filters that they used.

10:18:49 In the PREPIC2 study they just used a French single level retrievable filter call the ALN. They found no significant difference in the recurrent pulmonary embolism rate. I should say symptomatic pulmonary embolism rate.

10:19:03 But my major criticism of that was they didn't look for pulmonary embolism, they just relied on whether the patient had a major symptom to determine whether they had a pulmonary embolism or not. So I think they missed a lot of the -- well, they missed all the asymptomatic pulmonary emboli 10:19:18 that could be occurring. And they're just as dangerous as symptomatic pulmonary embolism, by the way.

Q So, Doctor, what do the PREPIC1 and PREPIC2 studies mean for you in your practice?

A Well, the PREPIC1, I mean, despite all the criticisms of 10:19:33 the study that I have, did show that IVC filters decrease the recurrent pulmonary embolism rate even on top of an already well-known treatment called anticoagulation.

PREPIC2, I don't really have a lot to comment on because I don't think it really told us very much at all.

10:19:53 Q Did either the PREPIC1 or the PREPIC2 study involve a Eclipse filter or any other Bard filter?

A No.

Q And, Doctor, let's kind of carry that forward a little bit. Other than the two PREPIC studies, are there any other 10:20:12 randomized clinically controlled prospective studies on IVC

10:20:17 filters?
A No.
Q And has a study ever been done where searchers compared a population of patients who were -- who received an IVC filter
10:20:28 but took no anticoagulant versus a group of patients who did not receive any treatment at all?
A I've heard of one underway, but I don't know of any study like that that's been published, to my knowledge.
Q And would there be certain issues that researchers may
10:20:52 encounter if they try to conduct such a study to compare a group of patients who had received filters who are at risk of pulmonary embolism versus patients who are at risk of pulmonary embolism but received no treatment?
A There would be major ethical problems with a study like
10:21:08 that, yes.
Q So, Doctor, if there are no studies that are these kind of Level 1 randomized clinically controlled studies about filters that showed their efficacy, is there other literature that you rely on to support your opinions?
10:21:24 A Yes. There are lots of what we call observational studies. These are nonprospective -- they can be prospective, but they're nonrandomized and controlled studies that do show a benefit of IVC filters.
Q And can you give the jury some overview of the types of
10:21:43 studies you looked at and what your take away was from those

studies?

A Right. So there's a doctor named Dr. Paul Stein who does a lot of database studies, and he came out with a publication, and I believe it was 2012, where he looked at what's called the national inpatient sample. This was looking at millions of hospitalized patients with a diagnosis of pulmonary embolism.

And he basically looked at those patients that received a filter and those that did not. And overall he found a case fatality rate in those patients that received the filter to be lower than the patients that did not receive a filter.

In particular, he looked at several different groups that were very interesting. These were unstable pulmonary embolism patients, meaning their blood pressure was low, they were at -- they had what we call a high risk pulmonary embolism. And in those patients that received thrombolytic therapy, because as interventional radiologists sometimes we try to dissolve the clot emergently to try to save the patient's life in those patients, and these are the types of patients that he's talking about in that case.

In that subset of patients, the patients that received a filter had a case fatality rate of 7.6 percent, whereas the patients that did not receive a filter had a case fatality rate of 18 percent.

10:23:19 In another subgroup with the same type of patients that did not receive thrombolytic therapy, so they were also unstable, that case fatality rate was 33 percent, whereas the patients that did not -- that received the filter, whereas the
10:23:34 patients did not receive the filter, their case fatality rate was 51 percent.

Q And are there other articles that you saw --

A I reviewed quite a few of them. There's another one that came out in 2014 by the same -- and Dr. Decousus, who was the
10:23:55 lead author of the PREPIC1 study was an author of this particular study, the lead author was named Dr. Muriel, and they -- this is a multinational, multicenter study. It was a prospective cohort study. It wasn't randomized. But they looked at over 40,000 pulmonary embolism patients in
10:24:17 hospitals -- that were hospitalized.

And they picked 344 of the patients that had a filter, and they matched those to 344 other patients that did not receive a filter. They all had pulmonary embolism. And they found that the risk adjusted pulmonary embolism mortality
10:24:37 rate was much lower for the patients that received a filter. They had a mortality rate of 1.7 percent, whereas the patients who did not receive the filter had a mortality rate of 4.9 percent. That is almost a three-fold reduction in the risk adjusted pulmonary embolism mortality rate by having a
10:24:59 filter placed.

10:25:03 Q Dr. Morris, do these large retrospective studies that you reviewed, do they support your opinion that IVC filters are effective in stopping PE?
A Yes. But the Muriel study was a prospective study.
10:25:17 Q And do doctors in clinical practice, do you have to make medical decisions every day based on information that lacks these kind of Level 1 randomized clinically controlled prospective trials?
A Yes.
10:25:31 Q Doctor, let's turn our attention to the second thing that you said that you were relying on about the effectiveness of IVC filters and. I believe you said that that was your personal experience with filters?
A Yes.
10:25:42 Q And can you start off by telling us, just generally, in your group at the University of Vermont, approximately how many filters do you think your group has placed?
A Well, since I've been there since 1991, we've placed around 2,000 IVC filters. And I've been one of two
10:26:01 interventional radiologists and, more recently, one of four interventional radiologists over the last 27 years. I estimate that I placed around 800 IVC filters, in general.
Q And can you give us a rough estimate of approximately how many retrievable filters you would have removed?
10:26:18 A Somewhere between 1- and 200. That's a rough estimate.

10:26:23 Q And of the filters that you have used during the course of your career, have the majority of those filters been Bard IVC filters?
A Yes.
10:26:32 Q And have they been Bard IVC retrievable filters?
A Yes.
Q And did you also use Bard permanent filters, like the Simon Nitinol filter?
A We did use that, yes.
10:26:44 Q And, Doctor, other than those Bard family of filters, have you used various filters that were made by different manufacturers?
A We have used lots of different filters, yes.
Q Okay. Let me ask you about some of your experience, just
10:27:00 in a sort of historical way. When you first were in your training, did you have experience with patients who had received a filter called the Mobin-Uddin umbrella filter?
A Yes, we did.
Q And tell us about that.
10:27:13 A Well, Dr. Mobin-Uddin was a professor of surgery at Ohio State when I was a resident, and although he developed the Mobin-Uddin umbrella when he was at University of Florida and introduced in 1967, it was pretty much replaced by the Greenfield filter early on in the early seventies, when the
10:27:33 Greenfield filter came out in 1973. But since he was Ohio

10:27:38 State, he still had a cohort of patients that he had placed his umbrella in, and so we would still see those patients occasionally for various reasons. So I was familiar with the Mobin-Uddin filter from that standpoint.

10:27:51 Q Was the Mobin-Uddin filter one that could be retrieved?

A No.

Q And can you tell the jury how that filter was placed in a patient?

A It was placed by a surgical cut down in the groin vein

10:28:04 called the femoral vein. And back then the only surgeons were replacing these. I never actually saw the delivery device, but I was told by some of the older surgeons that it was a large cannula that the umbrella was pushed through and delivered, in similar fashion to the filters that we place

10:28:23 today.

Q And so you mentioned the Greenfield filter. And tell us about your experience with that.

A At Ohio State we placed a lot of Greenfield filters, and placed a lot of them at University of Vermont as well. But

10:28:39 that was developed by Dr. Greenfield and introduced in 1973, became the gold standard IVC filter. It's a permanent IVC filter. It's conical in shape, it was the first filter that looked like an actual umbrella, and it was unique in that it could collect quite a bit of clot and still keep the IVC, or

10:29:03 inferior vena cava open, because the Mobin-Uddin filter, its

competitor, had a really high IVC occlusion rate. It would trap clots just fine, but all that clot didn't have anywhere to go and it would block off the IVC, whereas the conical filter was a unique design.

I wish I had a picture to show you, to show you the difference in the design of those filters, but that was the filter of choice when I started my residency at Ohio State in 1986.

THE COURT: We're going to break at this point, Mr. Rogers.

We will resume, ladies and gentlemen, at 10:45.

(Recess taken from 10:29 to 10:45. Proceedings resumed in open court with the jury present.)

THE COURT: Please be seated.

You may continue, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor.

BY MR. ROGERS:

Q Dr. Morris, before we had our break, you were talking about some of the permanent filters that you had used earlier in your career. And you had talked to us about the Mobin-Uddin filter, as well as the Greenfield filter. Were there other permanent filters that were used in the early portions of your career?

A Yes. After the Greenfield filter, at least the first version of the Greenfield filter, because there were three

versions: One was titanium and two of the others were stainless steel, the Greenfield. Shortly after that the Cook Bird's Nest filter was introduced in, I believe, 1985 or so. And we, of course, used that. And we still have it in our inventory now at University of Vermont Medical Center. That was unique in that it was the only filter that could be placed in very large diameter inferior vena cava, the so-called mega cava.

Then the Simon Nitinol was introduced in the late 1980s, around the same time the LGM VenaTech. These are all permanent filters, by the way. The VenaTech filter was similar in design to the Greenfield filter.

Then after that we had some experience with the TrapEase filter. That was also a permanent filter in the 1990s.

Then the Cook Tulip filter was introduced in the early 2000s, and we pretty much switched over to placing that because we could retrieve it.

Q Let me stop you there for a moment. Was that the first retrievable filter that you had experience with?

A Yes.

Q And about when was that introduced in the marketplace?

A I don't remember exactly. Somewhere around 2001, 2002.

Q And what were the limitations as to how the Cook Tulip filter could be used and how long it could remain in a

10:48:09 patient?
A So the Cook Tulip filter was what we called an optional filter. It could stay in place as a permanent filter, but could also be retrieved when there was no longer an indication
10:48:26 for IVC filtration.
But we believed that it could only be retrieved within the 14 to 21 days. So it had a limited duration of filtration. So at that time we were placing it into a lot of younger trauma patients and we wanted to make sure we got the
10:48:45 filter out. So we would have to bring these patients back down to the interventional radiology suite every 14 to 21 days and perform an invasive procedure under sedation by retrieving the filter but not taking it out of the body, just moving it about a centimeter either up or down and redeploying it so it
10:49:09 had a new, fresh reattachment site, and we had to continue to doing that for the duration of the life of the filter. Sometimes these patients needed to keep these filters in up to six months. You can imagine how many times we had to perform that repositioning procedure on the Cook Tulip filter.
10:49:29 Q When was the Recovery filter introduced in the market?
A I believe it was late 2003, but I think we started placing it in 2004.
Q And how long could the Recovery filter remain in a patient prior to potential retrieval?
10:49:45 A Well, at least six months, but soon after we started

placing it there were reports coming out that it could be retrieved after a year of duration.

Q And what was the general reaction in the interventional radiology community about this filter that could remain in patients for longer periods of time and still be retrieved?

A We were ecstatic because we no longer had to perform these very cost-inefficient and onerous repositioning procedures on the Cook Tulip filter. So this new Bard Recovery filter sort of revolutionized the IVC filter world at that time.

Q Have you used the family of Bard retrievable filters since that time?

A Yes. All of them.

Q And have you implanted and retrieved all of the Bard family of retrievable filters?

A Yes.

Q And would that include the Eclipse filter?

A Yes.

Q And, Doctor, do you have a reasonable degree -- an opinion to a reasonable degree of medical certainty as to whether the Bard family of retrievable filters, including the Eclipse filter, is safe and effective?

A I do, yes.

Q And what is that opinion?

A That they are safe and effective.

Q Doctor, let's talk a little bit about the retrieval of a

filter that can be removed. Can you tell us what a doctor should consider when they're caring for a patient about the potential removal of a filter?

A Well, every patient is different, so we look at the risk/benefit ratio of leaving the filter in versus taking it out on every single patient. But, in general, if the indication for IVC filtration has expired, and that can happen for several reasons. One is the patient may be able to anticoagulated at some point. And another might be the patient is ambulatory and no longer at bedrest. Or the filter has been in place for up to three months or six months, however long the physicians believe the patient needs to be protected against recurrent pulmonary embolism. These are some of the reasons why we look at each individual patient and make that determination whether it's best to get that filter out at that time.

Other patients may not have a continued indication for IVC filtration but it might be more compassionate to leave it in those cases. These may be patients that have a limited life expectancy of less than one year. Patients with metastatic cancer that are not going to do well and why subject them to another invasive procedure.

So we look at each individual patient on a case-by-case basis.

Q And do you have in place at your hospital a program that

10:52:45 focuses on the retrieval of IVC filters that can be retrieved?
A Yes, we do.
Q And tell us about that, please.
A Well, we -- in 2006 we conceptualized a multidisciplinary
10:52:59 clinic that looked just at IVC filters that we placed. And at that point our trauma surgeons were also placing some filters, so they were part of it as well, but most were placed by interventional radiologists. And after we placed a filter, we send the patient after -- at three months to our hematology
10:53:19 specialists who are just -- are world-renowned experts in venous thromboembolic disease, and they make the determination on a case-by-case basis of whether they recommend the patient be retrieved or not. And so that's been going on ever since -- I believe we actually started in 2007, and that was
10:53:42 the subject of our paper, the five-year experience early on that we published that came out just last year.
Q And so it was a study performed in regard to the program that you have about retrieving filters?
A Yes. Yes, there was.
10:53:57 Q And I think you mentioned a moment ago that study was ultimately published.
A Yes, it was.
Q Was that subject to the peer-review process?
A Yes.
10:54:04 Q Tell us, what were the general results of that study?

10:54:07 A Well, we compared the five-year intervention patients to historical controls. Meaning it was a program that we, as interventional radiologists, performed on our own. And we were retrieving filters at a rate of 23 percent historically.

10:54:22 And when our hematologists got involved with this multidisciplinary clinic, that rate went up to 45 percent. Now we're somewhere between 70 and 80 percent. But it was a gradual increase in the IVC filter retrieval rate.

Q Have there been shifts over the course of your career in 10:54:42 the way that doctors have approached the potential retrieval of IVC filters that can be retrieved?

A Yes.

Q And describe that for the jury, please.

A Well, early on in the era of the retrievable filters, we 10:55:00 were not very diligent in following up our patients and looking at ways to get the filters out. We relied a lot on the clinicians, the primary care physicians, maybe trauma surgeons, to refer those patients back to us. And that's one reason why the IVC filter retrieval rate was so low early on.

10:55:22 With time, we realized that we have to be a lot more rigorous in evaluating these patients and clinically assessing them and determining whether or not these filters should come out or not.

MR. ROGERS: Can we pull up Exhibit 6991, please.

10:55:41 BY MR. ROGERS:
Q Dr. Morris, do you see Exhibit 6991 on your screen?
A Yes, I do.
Q Can you tell us generally what this is.
10:55:59 A Well, this is the first of two communications from the FDA regarding the --
MR. COMBS: Objection, Your Honor. Nondisclosure.
THE COURT: Where is this in the report?
MR. ROGERS: Your Honor, on page 6 of the report,
10:56:15 bottom of the page.
MR. COMBS: This was not disclosed as an exhibit to be used with this witness, that I'm aware.
THE COURT: Let's talk at sidebar for a minute, Counsel.
10:56:32 (Bench conference as follows:)
THE COURT: Where exactly is the disclosure?
MR. COMBS: Recommendation --
MR. ROGERS: 6, if you look at the bottom of the page. About four lines up from the bottom. FDA --
10:56:44 THE COURT: I see that. And where is it disclosed as an exhibit?
MR. ROGERS: For this trial, we sent it to them yesterday and said we plan to use it.
MR. COMBS: What was the number?
10:56:56 THE COURT: What's the number?

10:56:57 MR. ROGERS: 6991.
MR. COMBS: I stand corrected, Your Honor.
THE COURT: Okay. All right.
(Bench conference concludes.)
10:57:11 THE COURT: Thank you, ladies and gentlemen.
BY MR. ROGERS:
Q Dr. Morris, I believe you were explaining to the jury what this document was.
A Yes.
10:57:27 Q Can you continue, please.
A Okay.
So this was written by the FDA and they call it a initial communication, and it was regarding the -- basically the lack of diligent follow-up of these patients that had
10:57:49 retrievable IVC filters in place and --
Q Doctor, let me cut you off for just a moment, if you don't mind.
MR. ROGERS: Your Honor, I would like to move Exhibit 6991 into evidence.
10:58:03 MR. COMBS: Objection. Hearsay grounds, Your Honor.
MR. ROGERS: Your Honor, it falls under exception 803(8) as a public record.
THE COURT: What is your response on 803(8), Mr. Combs?
10:58:17 MR. COMBS: I'm not sure they've established any

10:58:20 foundation for that exception, Your Honor, and I'm not sure this witness can establish that foundation.

THE COURT: Hold on just a minute.

Objection is overruled. 6991 is admitted.

10:58:38 (Exhibit 6991 admitted.)

MR. ROGERS: Thank you, Your Honor.

Your Honor, may we publish this to the jury, please?

THE COURT: You may.

BY MR. ROGERS:

10:58:47 Q Dr. Morris, now that the jury has this up on their screens, I want to at least give a little orientation about this document.

MR. ROGERS: Scott, would you mind highlighting the very top where it says "FDA."

10:58:57 BY MR. ROGERS:

Q And so is this what you were describing earlier, Dr. Morris, as being a communication from the FDA?

A Yes.

Q And, briefly, do you mind reading the title of the

10:59:10 communication.

A Yes. Inferior Vena Cava IVC Filters. Initial Communication: Risk of Adverse Events with Long Term Use.

MR. ROGERS: And, Scott, if you don't mind, would you take that down. And there's a section there that says

10:59:23 Audience, can you pull that out, please.

BY MR. ROGERS:

Q And so, Dr. Morris, what was the intended audience for this communication?

A Well, it says here Emergency Medicine and Surgery. But I think it was really intended for all physicians that had anything to do with IVC filters. That would include interventional radiologists, surgeons, primary care physicians, hematology specialists. Everyone.

Q Okay. So --

MR. ROGERS: Would you take that down, please.

And, if you would, let's pull out the section called Issue and Background, both of those two sections.

Thanks.

BY MR. ROGERS:

Q And so if you don't mind, Dr. Morris, can you give us some more background on this and what was your understanding of what was going on at the time?

A Okay. So early on with the retrievable filters, we were taking out a good percentage of them, even though it wasn't as high as we thought it would be. So we were actually imaging all these filters that had never been done before.

We were not retrieving permanent filters. When we placed permanent filters, we put them in and often never saw the patient again and never looked at any of their imaging they might have.

11:00:40 When these first IVC -- retrievable IVC filters were placed, there were reports of complications with them. They got very specific imaging looking for some of these complications that we've already talked about. And so the 11:00:55 FDA, through their MAUDE database, got some of these reports of these complications, and then they also noticed at the same time that a lot of these filters were not being removed when there was no more indication for IVC filtration. And they figured out there's really a failure of communication between 11:01:12 the implanting physicians and those physicians taking care of the patients long term. So it's really an omission of this failure of communication that is being denoted here.

Q In the last sentence before it reaches the Background section --

11:01:28 MR. ROGERS: Can you highlight that, please.

BY MR. ROGERS:

Q And, Dr. Morris, would you mind reading that for the jury.

A Sure. "Known long-term risks associated with IVC filters include but are not limited to lower deep vein thrombosis, 11:01:45 DVT, filter fracture, filter migration, filter embolization, and IVC perforation."

MR. ROGERS: And can you take that down, please.

BY MR. ROGERS:

Q What is the date of the document when this was released 11:01:58 from FDA?

11:01:59 A This would have been 2010. 8/9/2010.
Q How does that relate to when the Eclipse filter was on the market?
A I know it came out --
11:02:10 MR. COMBS: Nondisclosure as to Eclipse.
THE COURT: Is that in the report?
MR. ROGERS: I doubt it, Your Honor. I'll move on.
THE COURT: All right.
BY MR. ROGERS:
11:02:22 Q Dr. Morris, was this particular -- first of all, let's look at the Recommendation section, if you would.
MR. ROGERS: Could we pull that out.
BY MR. ROGERS:
Q And so, Dr. Morris, if you would, would you mind reading
11:02:33 the first sentence under the Recommendations section.
A Yes. "FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed."
11:02:48 Q And is that consistent with what you were describing to the jury earlier?
A Yes.
Q And does this particular safety communication from FDA, does it mention any specific manufacturer of IVC filters?
11:03:03 A No.

11:03:03 Q Does it mention any particular model of IVC filter?
A No.
Q And so, Doctor, with your practice, what sort of impact did this have in the -- in the interventional radiology
11:03:21 community?
A Well, I think most interventional radiologists knew about this issue. This -- but the medical -- general medical community did not know about the issue, and I think this had more of an impact on the general medical community. But we
11:03:39 had already been talking about these issues for many years prior to this.
Q Okay.
MR. ROGERS: Can we take that down, please.
And would you mind pulling up Exhibit 6992.
11:03:52 BY MR. ROGERS:
Q And, Dr. Morris, would you describe generally what this document is? This 6992.
A This came out four years later and it's an update of the 2010 initial communication.
11:04:09 MR. ROGERS: And, Your Honor, I would at this time move Exhibit 6992 in evidence.
THE COURT: Exhibit 6992? You said 992.
MR. ROGERS: Excuse me. Yes, Your Honor, 6992.
MR. COMBS: No objection, Your Honor.
11:04:21 THE COURT: Admitted.

(Exhibit 6992 admitted.)

MR. ROGERS: May I publish?

THE COURT: You may.

BY MR. ROGERS:

Q Dr. Morris, if you don't mind, what's the title of this communication?

A FDA Safety Communication: Removing Retrievable Inferior Vena Cava Filters.

Q And I think you said this a moment ago, but the date of this is what?

A August 9, 2010.

MR. ROGERS: And if you would go down, please, Scott, a little bit and pull out the section on Audience.

BY MR. ROGERS:

Q And, Dr. Morris, according to the FDA, who is this communication directed to?

A "Physicians who implant inferior vena cava, IVC, filters and clinicians responsible for the ongoing care of patients with these devices."

MR. ROGERS: And let's pull out the Recommendations and Action sections.

BY MR. ROGERS:

Q And so, Doctor, would you mind describing for the jury what the recommendations of FDA were at this point in time in 2014?

11:05:17 A "The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed."

11:05:31 Q And did this communication reference any specific manufacturer or model of IVC filter?

A No.

Q And what impact did this have in your practice as an interventional radiologist?

11:05:42 A Well, it really didn't have any impact on my personal practice because we were already following these recommendations many years before. It did give us a little more impetus to publish our study that we were completing around this time. And it did generate, I think, even a little

11:06:02 more notoriety in the general medical community.

Q And do you feel like it addressed that disconnect between the interventional radiology community and the community of physicians, like family care doctors and internists who may refer a patient to an interventional radiologist to have a

11:06:22 filter placed?

A Yes, I think it spelled it out in black and white.

Q Doctor --

MR. ROGERS: We can remove that, please.

BY MR. ROGERS:

11:06:29 Q Let's move on and talk a little bit about potential risks

and complications with IVC filters. You've addressed that a little bit, but I want to talk to you in a little more detail.

What are some of the known risks of IVC filters?

A Well, conical filters can tilt. I can list all of them just in general, but perforation, penetration, migration. Almost basically all filters can fracture. And then fracture embolization and thrombosis, which includes IVC thrombosis and recurrent deep venous thrombosis at the puncture site, for instance. Those types of things.

Q You said fracture embolization. What do you mean by that?

A If a filter fractures and that fracture fragment becomes detached from the filter, it can stay in place or it can migrate away from its original location and can even embolize with the flowing blood towards the heart, and it can go through the heart and into the pulmonary arteries.

Q Did the complications you described occur with both permanent filters and retrievable filters?

A Yes.

Q Doctor, is there anything you're aware of that would be considered a perfect IVC filter?

A No.

Q Is there always room for improvement with IVC filters?

A Yes.

Q Doctor, let's talk a little bit more about permanent filters. In your experience, did they get as much -- when you

11:08:07 have a patient who has a permanent filter, do those patients tend to get as much clinical follow-up regarding their filter and imaging follow-up as a patient who has a retrievable filter?

11:08:18 A In our practice, patients with permanent filters did not get any follow-up per se about their IVC filters at all.

Q What do you think that means as far as the numbers of complications that are seen with permanent filters versus retrievable filters?

11:08:37 A I think some of it is related to the difference between the generalized imaging follow-up that we've applied to retrievable filters, as opposed to permanent filters, so we see more complications partly because of that.

Q Let's shift gears and talk about the Simon Nitinol filter.

11:09:02 I believe you told us earlier that is a filter you did implant at some point?

A Yes.

Q When is the last time you would approximate you would have implanted a Simon Nitinol filter?

11:09:12 A Late 1990s, although one of my partners implanted a series of Simon Nitinol filters in maybe mid 2000s. But I gave up the Simon Nitinol filter in the late 1990s.

Q And what was your personal experience with the Simon Nitinol filter?

11:09:26 A It was not my favorite IVC filter. It did have an

11:09:30 advantage in that it was low profile. So that means that it could be placed through an arm vein. It was the only filter that could be placed in that manner. So sometimes we'd have a patient that had no, what we say, IV access, and that means 11:09:45 both of their femoral veins are clotted off, there's no way to get into their venous system that way, and both of their jugular and subclavian veins up in their neck, they were all clotted off, and so it may have been the only access we had was through an arm vein. So we place them at that time.

11:10:01 And sometimes we also placed what's called a PICC line, which is an arm IV access. And if that patient also needed a filter, we were already in the venous system through the arm, so we would leave a Simon Nitinol filter in place because we already had that access available to us.

11:10:22 MR. ROGERS: Can we bring up Exhibit 7226, please.

BY MR. ROGERS:

Q Doctor, do you see Exhibit 7226 on your screen?

A Yes.

Q And can you tell us what the title of this document is.

11:10:39 A This says Long Term Results of the Simon Nitinol Inferior Vena Cava Filter.

Q Is this a medical article that was published in the literature?

A Yes.

11:10:50 Q Doctor, do you know what journal this was published in?

11:10:53 A Cardiovascular Radiology.
Q Is that a journal that is a peer-reviewed journal?
A Yes. It's a European journal.
Q Would you consider articles that are published in that
11:11:05 journal to be reliable?
A Yes.
Q And would you consider this particular article to be
reliable?
A Can I correct myself one second? It's actually published
11:11:14 in European Radiology and I misread. Cardiovascular Radiology
is the subtitle of European Radiology.
But, yes, it is reliable. Yes.
Q Is this an article you're familiar with?
A Yes.
11:11:28 Q Can you tell the jury, please, when this article was
published?
A I believe it came out in 1998.
Q And was what is the general subject matter of this
article?
11:11:40 A They looked at the Simon Nitinol filter, which is the
permanent filter, and they, I believe, had 114 patients but
they were able to subject 38 of those to a pretty intensive
radiologic follow-up, which included an ultrasound, duplex
ultrasound, looking at whether their inferior vena cava was
11:12:02 open or to not; a radiograph, meaning abdominal X-ray; and

also a CAT scan. They were able to do that on 38 patients and then provide the radiographic follow-up at almost, I believe, three years after these filters on average were in place.

Q And, Doctor, did the authors of this study publish information about the complications they saw with the Simon Nitinol filter?

A Yes, they did.

MR. ROGERS: Scott, would you mind going to the third page and pulling up Table 2.

BY MR. ROGERS:

Q And, Doctor, can you tell the jury what the complication information was that's reported in this study.

A They found quite a few complications on their follow-up imaging. The most striking one was 95 percent perforation rate. That means 95 percent of these filters had perforated the IVC. And, in addition, 76 percent of the filters have what we call today a grade 3 perforation, meaning one of the struts was interacting with another structure outside of the inferior vena cava.

In addition, they had a fracture rate of the struts, not the daisy wheel. You may have heard how the Simon Nitinol filter had a continuous loop on top and if that fractured it wasn't that big of a deal because it wouldn't become detached and embolize. But if they just looked at the struts themselves, there was a 16 percent fracture rate of the

11:13:36 struts. And those could become detached and embolize, potentially.

And then there was another high percentage of what's called the eccentric positioning, which in the Simon Nitinol 11:13:53 basically meant that it deformed. The daisy wheel would often bend over itself and become deformed within the inferior vena cava and basically, I thought, predispose the inferior vena cava to thrombosis. And that happened 68 percent of the time.

Q Doctor, you've obviously been talking about complications 11:14:18 seen with the Simon Nitinol filter. But are the complications of tilt, migration, fracture, and embolization complications that are well-known to happen in virtually all IVC filters?

A Yes.

Q And has that been known for a number of years within the 11:14:35 interventional radiology community?

A Yes. There are certain designs that may not be able to tilt, for instance. The TrapEase and OptEase, because of their design, physically can't tilt. Although I have seen a horizontal -- somehow a TrapEase filter was horizontal in the 11:14:54 IVC, but that is extremely rare.

Q Doctor, let's again shift gears and talk specifically about the Eclipse filter. Have you had an opportunity to review the instructions for use with --

MR. COMBS: Objection, Your Honor. Nondisclosure to 11:15:08 the Eclipse filter.

THE COURT: Where is that, Mr. Rogers?

MR. ROGERS: Your Honor, may we approach?

THE COURT: Sure.

If you want to stand up, ladies and gentlemen, feel free.

(Bench conference as follows:)

MR. ROGERS: Generally on page 10 of the report. Through page 12. The doctor discusses the Bard family of IFUs in general.

THE COURT: Where it talks about the Bard Denali IFU?

MR. ROGERS: Yes, Your Honor. Then if you continue to the bottom of page 11, he says these complications have been warned of in the various IFUs for the Bard family.

THE COURT: That's talking about -- okay. So it says this list of complications was present in the IFU for all Bard IVCs since the G2. Is that what you're talking about?

MR. ROGERS: Yes, Your Honor. And he does go on to specifically mention the Eclipse in the third line.

MR. COMBS: It's not in his reliance list, Your Honor.

THE COURT: What's not?

MR.COMBS: The Bard Eclipse IFU.

THE COURT: So what's the objection?

MR. COMBS: Nondisclosure.

THE COURT: He's being asked to testify about -- I

mean give his opinion about the IFU was disclosed; right?

MR. COMBS: His opinion about Bard IFUs, yes.

THE COURT: And that it's in the Eclipse it says right here.

MR. COMBS: There's nothing saying he reviewed that.

THE COURT: But the opinion is disclosed. They're asking him for the disclosure. I mean, you're saying it isn't disclosed. The opinion is disclosed.

MR. COMBS: He looked at the Bard Denali IFU and made a general statement applying to all of them.

THE COURT: Well, so the opinion is disclosed.

MR. COMBS: Not about the Bard Eclipse IFU. He can talk about the Bard Denali.

THE COURT: He says it was added to the Bard Eclipse IFU. That's what I'm not understanding.

What is it that you say -- what opinion is not disclosed?

MR. COMBS: I don't even know what he's going to ask him about yet. But this Eclipse IFU was not part of his reliance list in his report.

THE COURT: So what are you going to ask, Mr. Rogers?

MR. ROGERS: I was going to go through the complication section, which he reports here.

THE COURT: On the basis of the Eclipse IFU?

MR. ROGERS: Yes, Your Honor.

11:18:09 THE COURT: He says this is based on the Denali IFU; right?

MR. ROGERS: Yes, Your Honor, and refers generally all of this information since the G2 has been in the entire family of Bard filters and I think that sentence kind of 11:18:19 carries over from 11 to 12.

THE COURT: It seems to me if you're going to do it you need to do it the way it was done in the report. You need to do it with the Denali IFU and he says what he can say here, 11:18:37 that it was present in the IFU for all Bard IVCs since the G2. That is an opinion that was disclosed. But I don't think you can -- if this is all based on the Denali IFU, I don't think you can have him do it on the basis of the Eclipse IFU.

MR. ROGERS: May I raise one other thing?

11:18:56 THE COURT: Yeah.

MR. ROGERS: This is a notebook that Dr. Morris brought to his deposition for the MDL, and the notebook was identified at the deposition. He was asked a question about the contents of the notebook, about the IFUs that are in here, 11:19:11 and the Eclipse IFU is in the IFUs that he brought with him to the deposition.

THE COURT: Was it marked as an exhibit? Did he testify about it?

MR. ROGERS: He testified in the sense they asked him 11:19:22 about what did you bring and what is this.

THE COURT: Okay. Did he give opinions --

MR. ROGERS: He did not, Your Honor.

THE COURT: Then I think you need to proceed the way it is in the report.

MR. ROGERS: I will move on from this.

MR. COMBS: Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. ROGERS:

Q Dr. Morris, I'm going to try to wrap up here and ask you a few concluding questions.

A Okay.

Q Have you given all of the opinions today to a reasonable degree of medical certainty?

A Yes.

Q And, Doctor, is it your opinion the entire Bard family of filters are safe and effective?

A Yes.

MR. ROGERS: Thank you. I have no further questions.

THE COURT: Cross-examination?

C R O S S - E X A M I N A T I O N

BY MR. COMBS:

Q Good morning, Dr. Morris.

You didn't review any medical records of the plaintiff, Doris Jones, for your work in this case, did you?

11:20:43 A No.
Q And you didn't look at any internal documents from Bard in your work in this case?
A No.
11:20:50 Q And so if there's internal documents where the medical director of Bard expresses his opinion internally within Bard about the Simon Nitinol filter, you wouldn't know anything about that?
A No.
11:21:06 Q And if the medical director of Bard stated in an internal document that the Simon Nitinol filter had virtually no complaints, you have no way to address that because you did not see the document or talk to anybody at Bard about it; right?
11:21:20 A I did not see that, no.
Q And the Simon Nitinol filter was the predicate device to the Recovery filter. True?
A Yes. And the Greenfield.
Q And from reading the medical literature, you know that the
11:21:38 Recovery filter had been associated with some problems with migration and perforation, tilting, injuring patients. True?
A Can you repeat that again, please.
Q Yeah. From reading the medical literature, you're aware that the Recovery filter had reports of complications
11:21:56 including complications that injured patients?

11:21:59 A Yes.
Q And the Recovery filter's no longer on the market. True?
A True.
Q And Simon Nitinol filter is still on the market?
11:22:07 A No. Not true.
Q Not true?
A Not true.
Q You're also aware of literature talking about complications regarding the G2 line of filters; correct?
11:22:24 A Yes.
Q And when you talked about the Poletti article and the Simon Nitinol filter, when they were fractures of the struts that you talked -- you remember talking about fractures of struts in the Simon Nitinol filter as reported in the Poletti
11:22:40 article?
A Yes.
Q Those struts would stay below the umbrella of the filter. True?
A They didn't really talk about that. They said there were
11:22:48 no symptoms related to those fractures.
Q And in terms of comparing the Recovery, the G2, or other Bard filters to the Simon Nitinol filter, you're not aware of any medical literature comparing the two; correct?
A No.
11:23:11 Q And you've never seen any Bard internal documents

comparing the Simon Nitinol filter to other Bard retrievable filters as far as complications. True?

A True.

Q And you would agree that the knowledge within the medical community about Bard's retrievable filters, as expressed in the medical literature, shows as time went on there were more and more reports of complications with the Recovery and G2 line of filters. True?

A To a certain extent. There were some papers later on that showed some high complication rates. But early on there were not. So in general that could be a true statement, but it wasn't a linear rise in rates.

Q And you talked about how pulmonary embolism can be asymptomatic; right?

A Yes.

Q And a fractured filter can be asymptomatic. True?

A Yes.

Q And certainly you would agree that a filter can fracture and be in a location that may be dangerous but still be asymptomatic?

A I can't really answer that yes or no because sometimes filter fragments can embolize to the heart and they can be potentially symptomatic. But if they embolize all the way through the heart and to the pulmonary arteries, they're usually described as asymptomatic.

11:24:54 Q But they could embolize to places where they could be dangerous and still not yet show a symptom. True?
A They could go to a place where they could be dangerous, but they can also go to a place where they're not dangerous.
11:25:07 Q Fair enough.
And -- well, you would agree that a filter piece fracturing and embolizing, that generally poses a danger and risk to the patient. True?
A A rare risk.
11:25:27 Q And there haven't been any studies on filter fragments and the length of time that they will remain asymptomatic. True?
A Not true.
Q And once a filter fragment -- it's discovered that a piece of an IVC filter has broken off, that's something that the
11:25:57 doctor -- the patient has to deal with. True?
A I guess that's a little bit hard to answer just yes or no, but we do evaluate those patients and they may or may not be followed for a period of time. But sometimes they're not followed either.
11:26:20 Q It's something you would take seriously, though?
A Yeah. I don't discount anything that's related to a patient, no.
Q And filter fragments breaking off and embolizing is something that a medical device company should take seriously.
11:26:35 True?

11:26:36 A Well, like anyone, yes.
Q You talked a lot about the efficacy of IVC filters generally. And your opinion in this case is that IVC filters are effective in preventing pulmonary embolism. True?
11:26:51 A I believe so, yes.
Q Are you aware of an article published by Dr. Frederick Rogers in the Journal of the American Medical Association in May of 2017?
A Very much so, yes.
11:27:01 Q Dr. Rogers is a former colleague of yours. True?
A Yes.
Q And Dr. Rogers' article was a study that looked at 30 million trauma patients from 2003 to 2015; correct?
A Yes.
11:27:13 Q And his article and his study found as IVC filter usage declined, there was no change in the rate of pulmonary embolism reported in trauma patients; correct?
A That's what he said, yes.
Q And you would agree this article tends to refute the
11:27:30 hypothesis that IVC filters are effective in preventing pulmonary embolism. True?
A I don't agree with that because Dr. Rogers was looking at patients that did not have documented thromboembolic disease. They were placing them in patients prophylactic- -- trauma
11:27:46 patients prophylactically and that's an indication that we

gave up, and Dr. Rogers also gave it up, at University of Vermont Medical Center more than ten years ago because we don't believe that is a valid indication of IVC filters.

Q And Dr. Rogers has testified in this case that the hypothesis -- hypothesis of his study was that as IVC filter usage declined, pulmonary embolism rates would go up, and he's testified that this study did not validate his hypothesis.

Would you disagree with that?

A I do. And I know most of those authors on that paper, including the lead author Alan Cook and Steve Shackford, who is also on that paper. I'm not sure that they really looked at the diagnosis of pulmonary embolism in a manner that an interventional radiologist or radiologist would look like. So CT angiography, for instance, can detect a lot of asymptomatic pulmonary embolism. In fact, most pulmonary emboli are asymptomatic and if they're not looking for them, how do they know what happened to the pulmonary embolism rate?

Q You talked about the PREPIC 2 study, Doctor. And the PREPIC 2 study also found that the use of IVC filters did not decrease rates of pulmonary embolism. Is that true?

A That's what they found, yes.

MR. COMBS: Nothing further, Your Honor.

THE COURT: Any redirect?

MR. ROGERS: No, Your Honor.

THE COURT: All right. Thank you, sir. You can step

down.

MS. HELM: Your Honor, at this time defendants call Melanie Sussman by videotaped deposition. Her education and background are in the video.

THE COURT: All right.

(Video testimony of Melanie Sussman played.)

THE COURT: Let's stop the video here, Counsel.

We'll break until 1 o'clock, ladies and gentlemen.

(The jury exited the courtroom at 12:00.)

THE COURT: Please be seated. Or if you want to leave, that's fine. It will take me a minute to calculate the time.

Well, do you know how we're allocating the deposition time?

MS. HELM: Yes. The deposition has about two or three minutes left. The total time allocated to the plaintiff is four minutes.

THE COURT: Okay.

All right, Counsel, as of now plaintiff has used 25 hours and 53 minutes. Defendants have used 17 hours and 39 minutes.

We've handed you the jury instructions after our conversations on Friday. We've red-lined the stuff that's changed. And you'll be able to see the stuff that wasn't changed because it isn't changed. And we've given you a

verdict form that is essentially the Booker form with the things taken out that had to do with Dr. Cain and others.

I have a criminal sentencing today at 4:30, and so what I think I'd like to do is get any final comments from you on the jury instructions at 8:30 tomorrow morning, if you could look at those this evening.

Defendants, where are you in your estimate of whether you will get through with Mr. Carr today?

MR. NORTH: I'm sorry?

THE COURT: Mr. Carr. Where are you -- do you think you'll get through your direct on him today?

MR. NORTH: It's going to be a very close call one way or the other. He's the second witness. We've got -- we do have a deposition that we could play in between to stretch that out. But I'm just not sure.

THE COURT: Okay. And Mr. -- I can't remember which one of you raised the issue with me. Is it the FDA warning letter that you wanted to cover with Mr. Carr? Is that the issue --

MR. CLARK: That was the thought.

MR. O'CONNOR: Yes.

THE COURT: -- that you raised this morning?

Okay.

I've got to prepare for this criminal sentencing over the lunch hour. If I have time, I'll look at the FDA warning

12:03:51 letter. I'm not certain I'll have time. But I'll do my best. And if I can, I'll let you know when I come back in my conclusion on that.

MR. NORTH: Your Honor, I certainly can't tell the 12:03:59 plaintiffs how to try their case, but Mr. Carr had no role in filters by the time the letter was issued. And Mr. Modra, of course, was the point person and he will be here tomorrow.

THE COURT: Okay.

MR. O'CONNOR: Your Honor, then, if that's the case, 12:04:13 then understanding your schedule and based upon his representation, we can get it through Mr. Modra, Your Honor.

THE COURT: Okay. I'll be sure to look at it tonight so I get you an answer by tomorrow morning.

MR. CLARK: There is the one matter of the monthly 12:04:29 management reports. I have prepared, and forgive me because it has my highlighting and things like that, drafts --

THE COURT: When is it -- when is it that you want to use those?

MR. CLARK: With Mr. Modra.

12:04:42 THE COURT: Mr. Modra. Why don't you go ahead and bring them up. I probably won't look at those until this evening.

MR. CLARK: That's fine, Your Honor.

For the record, Your Honor, the ones that we would 12:04:50 propose not redacting the filter related complaint summaries

12:04:56 are 4504, 4522, 4519, and 4528. That's two before the implantation and two after.

And then also I'm going to hand the Court a work-in-progress draft of our 1006 summary with the 40 12:05:14 complaint summaries, as well as an exemplar of what the redacted monthly management reports would look like.

THE COURT: Okay.

MR. CLARK: May I approach?

THE COURT: Yeah.

12:05:26 So are you just giving me the four that have the attachments plus an example of a redacted version?

MR. CLARK: Plus the 1006 summary and 40 complaints.

THE COURT: Right. Okay. Thanks.

We'll see you at 1 o'clock.

12:05:39 MR. COMBS: Your Honor, I do have copies of the Stavropoulos and Trerotola runs. I know you're buried over the lunch hour. But if you could look at them. They're short.

MR. NORTH: We're not getting to those until 12:05:50 tomorrow.

MR. COMBS: If that's for tomorrow, that's fine.

May I approach?

THE COURT: What's the issue?

MR. COMBS: The cumulative testimony --

12:05:59 THE COURT: Oh, that's the one you raised this

morning?

MR. COMBS: Correct.

THE COURT: Let me ask this question: These are fact witnesses; right?

MR. COMBS: We believe their testimony that defense wants to use is all expert testimony. That's our position.

THE COURT: They're not designated experts; right?

MR. COMBS: Not by Bard, no.

THE COURT: So this doesn't fall under my direction that you can't use a designated retained expert on more than one issue. So, instead, it seems to me, if it isn't covered by that, the objection has to be based on a basic cumulative objection, really 403 objection.

MR. COMBS: Correct, Your Honor.

THE COURT: Okay.

MR. COMBS: Thank you, Your Honor.

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 29th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter